

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1966

No. 336

THE TOILET GOODS ASSOCIATION, INC.,
ET AL., PETITIONERS,

vs.

JOHN W. GARDNER, SECRETARY OF HEALTH,
EDUCATION AND WELFARE, ET AL.

No. 438

JOHN W. GARDNER, SECRETARY OF HEALTH,
EDUCATION AND WELFARE, ET AL., PETI-
TIONERS,

vs.

THE TOILET GOODS ASSOCIATION, INC., ET AL.

ON WRITS OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE SECOND CIRCUIT

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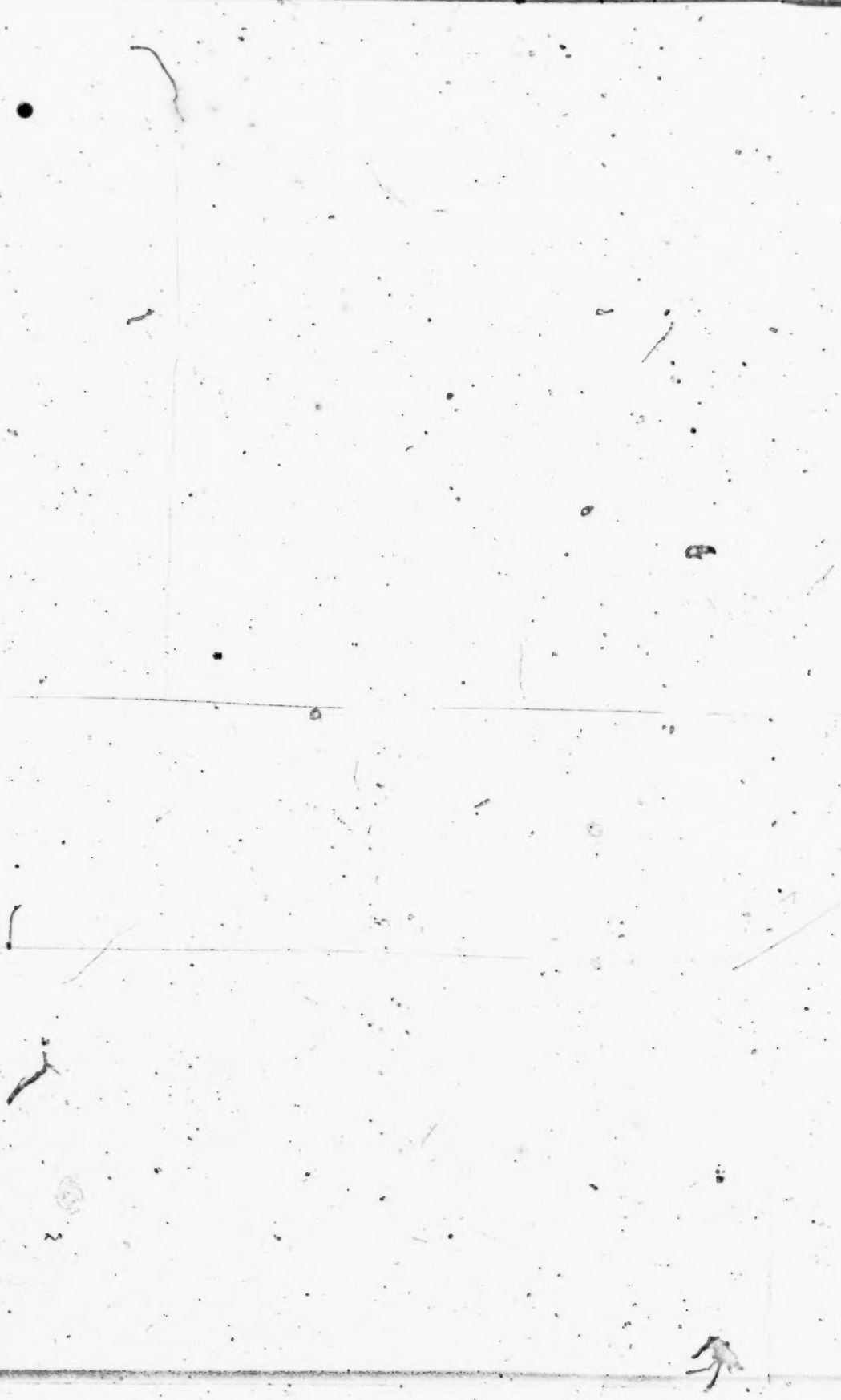
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[fol. A]

**IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT**

Appendix to Appellants' Brief—Filed February 9, 1966

**IN THE
UNITED STATES DISTRICT COURT**

SOUTHERN DISTRICT OF NEW YORK

63 Civ. 3349

**THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.;
AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE
BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.;
CHESEBROUGH-POND'S INC.; CHRISTIAN DIOR PERFUMES
CORP.; CLAIROL INCORPORATED; COLONIAL DAMES CO., LTD.;
FABERGÉ INC.; FRANCES DENNY, INC.; THE FULLER BRUSH
CO.; THE GEORGE W. LUFT CO., INC.; THE GILLETTE COM-
PANY; A. M. HANSEN, doing business as HOUSE OF HOLLY-
WOOD; HARPER METHOD, INC.; HELENA RUBINSTEIN, INC.;
HELENE CURTIS INDUSTRIES, INC.; HENRY/HARAN/HUTCH-
INGS, INC.; HERBOLD LABORATORY, INC.; JOHN H. BRECK,
INC.; KOLMAR LABORATORIES, INC.; LADY LENNOX COM-
PANY, INC.; LEHN & FINK PRODUCTS CORPORATION;
ARNOLD L. LEWIS, doing business as STUDIO COSMETIC
CO.; MAX FACTOR & CO.; MAYBELLINE CO.; MERLE NORMAN
COSMETICS, INC.; JACK B. NETHERCUTT, doing business
as NETHERCUTT LABORATORIES; NEUTROGENA CORP.; NU-
TRILITE PRODUCTS, INC.; OLD 97 COMPANY; PRIVATE LABEL
COSMETICS CO., INC.; PURITAN COSMETICS CO.; REVLON,
INC.; ROUX LABORATORIES, INC.; SHULTON, INC.; and
YARDLEY OF LONDON, INC., Plaintiffs,**

against

**ANTHONY J. CELEBREZZE, Secretary of Health, Education
and Welfare, and GEORGE P. LARRICK, Commissioner of
Food and Drugs, Defendants.**

COMPLAINT—Filed November 15, 1963

FIRST COUNT

Nature of Action, Parties, Jurisdiction, Venue and Authority to Bring Action.

1. This is an action for (a) a declaratory judgment that certain provisions of the regulations entitled "Part 8—Color Additives," published in the Federal Register, June 22, 1963, 28 Fed. Reg. 6439 *et seq.* (herein called "the Color Regulations"), are not in accordance with law, are in excess of the statutory jurisdiction, authority and limitations of the defendants, and are short of statutory right, and (b) for injunctive and other relief.

2. (a) The plaintiffs, other than The Toilet Goods Association, Inc. (herein called the "Association"), are engaged in the manufacture, distribution and sale in interstate and foreign commerce of cosmetics subject to the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), as amended, 21 USC §301 *et seq.* (herein called the "Act"). The plaintiffs join as such in this one action since they assert rights to relief in respect of and arising out of the same transaction and occurrence, and questions of law and fact common to all of them will arise in the action. The plaintiffs, other than the Association, are herein collectively called "the plaintiff companies." The plaintiff companies are members of the Association, which is a non-profit organization of cosmetic manufacturers whose members represent in excess of 90% of the annual sales of cosmetics in the United States.

[fol. B] (b) The following is the state of incorporation of each plaintiff, which is a corporation, and the principal place of business of each plaintiff:

Plaintiff	State of Incorporation	Principal Place of Business
The Toilet Goods Association, Inc.	New York (Membership Corporations Law)	1270 Avenue of the Americas, New York, New York
Anita D'Foged, Inc.	California	413 North Canon Drive, Beverly Hills, California
Avon Products, Inc.	New York	30 Rockefeller Plaza, New York, New York
Beauty Counselors, Inc.	Michigan	17108 Mack Avenue, Grosse Pointe, Michigan
Bonne Bell, Inc.	Ohio	18519 Detroit Avenue, Cleveland, Ohio
Bourjois, Inc.	New York	711 Fifth Avenue, New York, New York
Charles of the Ritz, Inc.	Delaware	11 East 58 Street, New York, New York
Chesebrough-Pond's Inc.	New York	485 Lexington Avenue, New York, New York
Christian Dior Per- fumes Corp.	New York	730 Fifth Avenue, New York, New York
Clairol Incorporated	Delaware	1290 Avenue of the Americas, New York, New York
Colonial Dames Co., Ltd.	California	1060 South Vail, Montebello, California
Fabergé Inc.	New York	395 South Broad Avenue, Ridgefield, New Jersey
Frances Denney, Inc.	Pennsylvania	5935 Woodland Avenue Philadelphia, Pennsylvania

Plaintiff	State of Incorporation	Principal Place of Business
The Fuller Brush Co. ..	Connecticut	East Hartford, Connecticut
The George W. Luft Co., Inc.	New York	34-12 36th Avenue, Long Island City, New York
The Gillette Company (The Toni Company Division)	Delaware	Gillette Park, Boston, Massachusetts
A. M. Hansen, doing business as House of Hollywood		777 East Gage Avenue, Los Angeles, California
Harper Method, Inc.	New York	1233 East Main Street, Rochester, New York
Helena Rubinstein, Inc.	New York	655 Fifth Avenue, New York, New York
Helene Curtis Indus- tries, Inc.	Illinois	4401 West North Avenue, Chicago, Illinois
Henry/Haran/Hutch- ings, Inc.	California	5815 Harold Way, Hollywood, California
Herbold Laboratory, Inc.	California	8008 West Third Street, Los Angeles, California
John H. Breck, Inc.	Delaware	115 Dwight Street, Springfield, Massachusetts
Kolmar Laboratories, Inc.	Delaware	Port Jervis, New York
[fol. C] Lady Lennox Company, Inc.	Tennessee	Memphis, Tennessee
Lehn & Fink Products Corporation	Delaware	445 Park Avenue, New York, New York

Plaintiff	State of Incorporation	Principal Place of Business
Arnold L. Lewis, doing business as Studio Cosmetic Co.		12232 West Olympic Boulevard, Los Angeles, California.
Max Factor & Co.	Delaware	1655 North McCadden Place, Hollywood, California
Maybelline Co.	Delaware	5900 Ridge Avenue, Chicago, Illinois
Merle Norman Cosmet- ics, Inc.	Nevada	9130 Bellanca Avenue, Los Angeles, California
Jack B. Nethercutt, do- ing business as Neth- ercutt Laboratories ..		3130 Bellanca Avenue, Los Angeles, California
Neutrogena Corp. (Na- tone Company Divi- sion)	California	Los Angeles, California
Nutrilite Products, Inc.	California	5600 Beach Boulevard, Buena Park, California
Old 97 Company	Florida	Tampa, Florida
Private Label Cosmet- ics Co., Inc.	New York	3545 Webster Avenue, Bronx, New York
Puritan Cosmetics Co.	Missouri	3719 North 14th Street, St. Louis, Missouri
Revlon, Inc.	Delaware	666 Fifth Avenue, New York, New York
Roux Laboratories, Inc.	New York	1841 Park Avenue, New York, New York
Shulton, Inc.	New Jersey	Route 46, Clifton, New Jersey
Yardley of London, Inc.	New Jersey	Union Boulevard, Totowa, New Jersey

(c) Various of the plaintiff companies which are incorporated or have their principal place of business in a state other than New York, are licensed to do business or are doing business in this judicial district.

3. Defendant Anthony J. Celebrezze is the Secretary of Health, Education and Welfare (herein called the "Secretary") and is the officer of the Department of Health, Education and Welfare (herein called the "Department") who is charged with the administration of the Act. The Secretary is authorized by Section 701(a) of the Act to promulgate regulations for the efficient enforcement of the Act, and by Section 706(b) and (c) of the Act to provide by regulation for separately listing color additives for use in food, drugs and cosmetics, for the certification of batches of color additives so listed and for the exemption of certain color additives from the requirement of certification. Defendant George P. Larrick is the Commissioner of Food and Drugs (herein called the "Commissioner") and is responsible for the supervision and direction of the Food and Drug Administration (herein called the "FDA"), an operating agency of the Department. 22 Fed. Reg. 1045, 1051. The Secretary has purported to assign to the Commissioner the functions vested in the Secretary and in the Department under the Act. 25 Fed. Reg. 8625. The Commissioner is the officer who promulgated the Color Regulations. Each defendant is an officer of an agency of the United States purporting to act in his official capacity or under color of legal authority.

[fol. D] 4. (a) The matter in controversy exceeds the sum or value of \$10,000, exclusive of interest and costs, and the action arises under the laws of the United States, namely, the Act, and more particularly, the amendment designated as the "Color Additive Amendments of 1960," enacted July 12, 1960, 74 Stat. 397 (herein called the "Color Additive Amendments"), and also the Administrative Procedure Act, 60 Stat. 237, as amended, 5 USC §1001, *et seq.*

(b) This Court has jurisdiction of this action by virtue of 28 USC §§1331(a) and 1337.

(c) This action is authorized by 28 USC §§2201 and 2202, and 5 USC §1009. The plaintiffs are persons suffering legal wrong because of the action of the Commissioner in promulgating the Color Regulations and are adversely affected and aggrieved by such action. This is a case of actual controversy which requires a declaration of the rights and other legal relations of the plaintiffs, as the interested parties seeking such declaration, and, more particularly, a declaration with respect to the invalidity of certain provisions of the Color Regulations, in the respects alleged in this complaint.

(d) Venue in this judicial district is proper by virtue of 28 USC §1391(e)(4).

Cosmetics Affected by this Count.

5. Various of the plaintiff companies manufacture, distribute and sell lipstick, rouge, eye makeup colors, nail polish and enamel, face powder, leg applications, suntan lotions and oils, hair dye products and other cosmetics intended for applying color to the human body, all of which products are in this count at times collectively called the "finished cosmetic products."

6. Cosmetics intended for applying color to the human body contain a dye or pigment. Dyes and pigments are also used to impart color to food, drug and cosmetic products. Dyes and pigments used for such purpose are known in the color, food, drug and cosmetic industries as, and are herein called, "color additives." The term "color additive" signifies that the dye or pigment is an ingredient of the food, drug or cosmetic product, as the case may be, and has been added for the sole purpose of imparting the desired color.

7. There are two categories of color additives, namely, (a) colors derived from natural sources, animal, vegetable or mineral, known in said industries as, and herein called, "natural colors," and (b) colors made by a process of synthesis, known in said industries as, and herein called, "synthetic dyes and pigments." Synthetic dyes and pigments are generally superior to natural colors from the standpoint of uniformity, tinctorial value and application properties and therefore became widely used as the color additive in foods, drugs and cosmetics. The synthetic dyes and pigments most widely used as such color additives are chemical compounds which are or can be derived from coal tar or coal-tar constituents, known in said industries as, and herein called, "coal-tar colors." Coal-tar colors are the color additives generally used to add color to the finished cosmetic products.

8. Color additives are manufactured by chemical and dye corporations (herein called the "color manufacturers"), who have wide experience and specialized skills in the chemical processes required to produce proper dyes and pigments. The color manufacturers sell the color additives to the food, drug and cosmetic manufacturers, including the plaintiff companies.

The Listing and Certification of Color Additives Under Prior Law.

9. The Secretary of Agriculture, who was charged with administration of the Food and Drug Act enacted in 1906 (34 Stat. 768) (herein called "the 1906 Act"), which was not applicable to cosmetics, promulgated a list of coal-tar colors, with specifications therefor, which were harmless and could be safely used in foods and confectionery. A voluntary practice was established of having color manufacturers submit to the Department of Agriculture samples from each batch of listed coal-tar colors to be analyzed for purity and compliance with the specifications for the listed coal-tar color, and to be certified as harmless, and a

batch so certified received an official certification number which accompanied the color through all subsequent packagings.

10. In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040) (herein called "the 1938 Act"), which extended statutory regulation to cosmetics, prohibited the adulteration or misbranding of any food, drug, device or cosmetic in interstate commerce, accorded statutory basis to such prior practice of listing coal-tar colors and having batches certified, and specifically applied such requirement to drugs and cosmetics, as well as to food products.

11. The 1938 Act provided, in Section 601 (a) and (e), that a cosmetic is deemed adulterated if "it bears or contains any poisonous or deleterious substance which may render it injurious to users" under certain conditions of use, or "it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604."

12. Section 604 of the 1938 Act provided as follows:

"CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

"Sec. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents."

13. The Secretary of Agriculture promulgated regulations which, among other things, prescribed the procedures to be followed for admitting coal-tar colors to listing and for obtaining subsequent certification of batches of such listed colors. Such regulations defined coal-tar colors as follows (21 CFR 135.1, 1949 ed.):

"(a) The term 'coal-tar color' means articles which
(1) are composed of or contain any substance derived

from coal tar, or any substance so related in its chemical structure to a constituent of coal tar as to be capable of derivation from such constituent; and (2) when added or applied to a food, drug, cosmetic, or the human body or any part thereof, are capable (alone or through reaction with other substance) of imparting color thereto."

14. There was thus established by the 1938 Act and the regulations thereunder, what was essentially a licensing system for coal-tar colors, as the color additives to be used in foods, drugs and cosmetics, involving pretesting and list-[fol. F] ing of the color additive and certification of color batches (hereinafter called the "color licensing system").

15. Pursuant to the color licensing system and prior to enactment in 1960 of the Color Additive Amendments, there were listed, with specifications, 118 coal-tar colors which had been established as harmless and suitable for use in foods, drugs and cosmetics. The coal-tar colors so listed included substantially all the color additives which were added to and used in lipsticks, rouges and nail polish and enamels, and in excess of 95% of such cosmetics sold in the United States contained as their color additive a listed and certified coal-tar color.

Emergency Which Resulted in Enactment in 1960 of the Color Additive Amendments.

16. On December 15, 1958 the Supreme Court, in *Fleming v. Florida Citrus Exchange*, 358 U. S. 153, sustained a position taken by the Secretary and the Commissioner, and held (a) that a coal-tar color to be listed and certified had to be entirely lacking in toxicity and be wholly innocuous and without any adverse physiological effect, (b) that the word "harmless" as used in the provision of the 1938 Act "for the listing of coal-tar colors which are harmless" had to be applied in an absolute sense, i.e., harmless per se, (c) that if a coal-tar color in any quantity, regard-

less of how substantial or concentrated, could produce any toxicity, it could not be listed as harmless and suitable for use in foods, drugs or cosmetics, even if established to be harmless with respect to a particular use in an article of food, drug or cosmetic, or with respect to the tolerances or quantities involved in such use, and (d) that the Secretary had no power to establish tolerances for the use of coal-tar colors in the finished product, though harmless in its particular use and application.

17. As a result of such position, the Secretary and the Commissioner reviewed all listed coal-tar colors and felt compelled to delist those which, on the basis of the absolute standard, could in any quantity or concentration produce some toxicity, even though such colors were in fact harmless in the quantity used in a particular article of food, drug or cosmetic.

18. The delisting of coal-tar colors which ensued and was anticipated, removed and threatened to continue to remove from the market products which had been widely sold and distributed and which had received extensive consumer acceptance, and which experience had established were harmless and safe in use, and such delisting threatened to destroy large segments of industry.

19. The Secretary prepared and sponsored a proposed bill for enactment by Congress, as a relief measure, which would empower him to allow color additives to be used in finished products with tolerance limitations, and to apply as the test for listing, the so-called "safe-for-use" principle, and thereby remedy the inflexibility of the 1938 Act, as interpreted to require application of the so-called "harmless per se" principle.

20. In transmitting the proposed legislation to the Speaker of the House, the Secretary explained the emergency requiring such remedial legislation. Such emergency was stated, in the same language as used by the Secretary, in the House Report on the proposed legislation, enacted

[fol. G] as the Color Additive Amendments (H. R. No. 1761, p. 9, dated June 7, 1960, 86th Cong. 2d Sess.), as follows:

"NEED FOR LEGISLATION

.

"Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

"The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which the Secretary of Health, Education, and Welfare believes could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health.

"There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use (including tolerance limitations and certification requirements) established by the Department of Health, Education, and Welfare."

21. The color licensing system voluntarily followed under the 1906 Act and prescribed by the 1938 Act was limited to coal-tar colors. Natural colors and synthetic dyes and pigments which were not coal-tar colors had not been subjected to the color licensing system.

22. The Secretary, in seeking remedial legislation to forestall the emergency above described, also proposed that the scope of the color licensing system be broadened to cover not only coal-tar colors, but all other colors.

23. The House Report (H. R. No. 1761, pp. 10-11) explained the second change to be accomplished by the proposed legislation, as follows:

"The bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term 'coal-tar color.' The bill would therefore establish common ground rules for all such colors.

"Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics. . . ."

24. The proposed legislation was based upon the definition of coal-tar colors, quoted in paragraph 13 hereof, which [for H] had been contained in the regulations for over twenty years, but substituted the term "color additive" for the term "coal-tar color" so as to cover both general categories of color additives, as described in paragraph 7 hereof, namely, the natural colors and the synthetic dyes and pigments. Thus, the definition of "color additive" contained

in the bill, and retained without change in the Color Additive Amendments (Section 201 of the Act), is as follows:

"(t)(1) The term 'color additive' means a material which—

"(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

"(B), when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

"(2) The term 'color' includes black, white, and intermediate grays."

25. Throughout the hearings on the bill, as well as in the House Report, it was emphasized by the Secretary, the Commissioner and other Government officials that the bill had a two-fold purpose, namely, (a) to relieve the emergency created by the delisting of colors, with the danger of driving out of business the color manufacturers and the food, drug and cosmetic manufacturers who used color additives as an ingredient of their finished product, and (b) to extend the color licensing system from coal-tar colors to natural colors and to synthetic dyes and pigments not coal-tar colors.

26. The Color Additive Amendments were proposed and enacted against the background hereinabove described.

The Color Additive Amendments of 1960.

27. The Color Additive Amendments, effectuating the two-fold purpose hereinabove described, authorized the Secretary to prescribe "a tolerance limitation . . . to assure that a proposed use of a color additive will be safe" (Sec. 706(b)(1)), and otherwise gave effect to the "safe-for-use" principle, and also defined color additives, as quoted in paragraph 24 hereof, to include natural and non-coal-tar colors (Sec. 201(t)).

28. Under the heading "Listing of Colors," such Amendments authorized the Secretary by regulation to "provide for separately listing * * * color additives for use in or on cosmetics" (Sec. 706(b)(1)), and under the heading "Certification of Colors," such Amendments further authorized the Secretary by regulation to provide for certification "of batches of color additives listed pursuant to subsection (b)" (Sec. 706(c)).

29. Unless the color additive received a new and separate listing and batches of the color additive were thereafter certified or exempted from certification, the use of such color additive in a food, drug or cosmetic product caused such product automatically to be deemed "unsafe" and "adulterated" (Sec. 706(a), 601(e)).

[fol. I] 30. Prior to such new listing, and in order to establish safety with respect to a particular use, the Color Additive Amendments require that each color additive be subject to scientific investigations, involving extensive and costly pharmacological and toxicological tests estimated to require two and one-half years for completion. To prevent removal from the market of all food, drug and cosmetic products which contain color additives, such Amendments, under the heading "Provisional Listings of Commercially Established Colors," authorized provisional listing of "color additives * * * pending the completion of the scientific investigations needed as a basis for making determina-

tions as to listing of such additives" (74 Stat. 397, 404, Title II, Sec. 203(a)(1); 21 U. S. C. fn. after §376(f)).

31. The Color Additive Amendments further provided that certain color additives would be "deemed" to be provisionally listed (a) if the color additive had been listed and certified on the day preceding the enactment date of such Amendments, namely, July 12, 1960 (having reference to coal-tar colors as the only colors required to be listed, and certified prior to such Amendments), and (b) if the color additive had been commercially used or sold prior to such enactment date for any use or uses in food, drugs or cosmetics (having reference to the colors not previously required to be listed and certified) (74 Stat. 397, 405, Title II, Sec. 203(b); 21 U. S. C. fn. after §376(f)).

32. The Color Additive Amendments provided a general period of two and one-half years from their enactment date for the provisional listing of color additives of the categories set forth in paragraph 31. Because "the scientific investigations needed as a basis for making determinations as to listing" of color additives might require more than two and one-half years, the Secretary was authorized, with respect to a particular provisional listing of a color additive, to extend such two and one-half year period on a showing that such scientific investigations were being carried to completion in good faith (74 Stat. 397, 404, Title II, Sec. 203(a)(1)(2); 21 U. S. C. fn. after §376(f)).

33. Pursuant to said statutory provisions for provisional listings, the Commissioner issued provisional regulations which set forth the names of color additives which were provisionally listed for use in foods, drugs and cosmetics. Such provisional listings included coal-tar additives which had been previously listed and certified, and also certain natural and non-coal-tar synthetic colors as to which listing and certification had not been previously required (21 CFR 8.501).

34. All the color additives provisionally listed by the Commissioner were colors, that is, dyes or pigments, and did not include finished cosmetic products or non-color ingredients of such products.

35. Promptly after enactment of the Color Additive Amendments and after consultation with authorized representatives of the FDA, the Association and various of the plaintiff companies undertook, in conjunction with the color manufacturers, to perform, or to arrange for the performance of, the scientific investigations and pharmacological and toxicological tests as to dyes and pigments to be used as color additives in cosmetics, as a basis whereby the Commissioner could make determinations as to listing such color additives. The plaintiff companies have not generally commenced or made or arranged for any such scientific investigations or pharmacological or toxicological tests as a basis for obtaining the listing of a finished cosmetic product, or [fol. 5] the ingredients therein, other than the dye or pigment. Until the promulgation of the Color Regulations on June 22, 1963, no recommendation or suggestion had been made by representatives of the FDA, or in public notices issued by it, that listings of finished cosmetic products or of such ingredients therein would be required under the Color Additive Amendments.

36. With respect to certain dyes or pigments, required scientific investigations could not be completed within the two and one-half year period prescribed by the Color Additive Amendments, which expired January 12, 1963, and the Commissioner extended the provisional listing of such dyes or pigments. At the present time, only dyes or pigments which have actually been provisionally listed by regulation for use in cosmetics are permitted in cosmetics, the so-called "deemed" provisional listings, referred to in paragraph 31, having expired on January 12, 1963.

37. The Act, as amended by the Color Additive Amendments, in effect, places foods, drugs and cosmetics, and

specific ingredients thereof, with respect to the safety of their composition, in three general categories, namely:

(a) Foods, old drugs and cosmetic products,—which can be manufactured and sold without advance approval or clearance by FDA, which, however, has the power, authority and responsibility of proceeding under the Act if the product contains a poisonous or deleterious substance which might render it injurious to users;

(b) New drugs and antibiotic drugs,—which cannot be sold without advance approval or clearance by FDA of the finished product, herein called “premarketing clearance;” and

(c) Specific ingredients of the product,—which, in the case of foods, are “food additives,” and, in the case of foods, drugs and cosmetics, are the dyes or pigments known as “color additives,” which specific color ingredients are subject to “premarketing clearance” by way of listing in appropriate regulations and by certification or exemption from certification under the color licensing system.

38. Premarketing clearance is not required by the Act for finished cosmetic products, but the safety of such products is governed by Section 601(a) with reference to a cosmetic which contains a poisonous or deleterious substance which might render it injurious to users.

The Color Regulations, and Their Unauthorized and Expanded Definition of Color Additives to Include Finished Cosmetic Products.

39. The Commissioner promulgated the Color Regulations, which, among other things, prescribed the color licensing system for color additives for use in food, drugs and cosmetics, and imposed with respect thereto additional requirements to give effect to the “safe-for-use” principle

embodied in the Color Additive Amendments. The Color Regulations were effective on the date of publication in the Federal Register, which was June 22, 1963, except that they grant a transitional period of two years for certain "coal-tar" hair dyes, and also provide that Section 8.30 of the Color Regulations, which relates to color additive mixtures, shall become effective one year after such publication.

[fol. K] 40. The Color Regulations initially gave the term "color additive" the same definition contained in the Act, as quoted in paragraph 24 hereof, but elsewhere the Color Regulations expanded the definition of the term by the following additional provision (Section 8.1(f)):

"Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives'."

41. The term "color additive", as defined by Congress in the Color Additive Amendments, and as used in the color industry and in the food, drug and cosmetic industries for over fifty years, means the ingredient in the food, drug or cosmetic which imparts color thereto, namely, the dye or pigment, whether synthetic or natural, and does not mean the finished product which contains the dye or pigment as one of many ingredients. All the color additives, as such term is defined by the Color Additive Amendments, used by each of the plaintiff companies in the finished cosmetic products, are listed in currently outstanding provisional regulations promulgated by the Commissioner. Finished cosmetic products are not listed in any currently outstanding regulation within the meaning of Section 706(a) of the Act, and the manufacture, sale and distribution by the plaintiff companies of finished cosmetic products constitute, according to the effect of the definition of "color additive" contained in the Color Regulations, an adulteration within the meaning of Section 601(e) of the Act.

42. By this expedient of expanding the meaning of the term "color additive" and by defining it to include the fin-

ished cosmetic product which contains the color additive, the Commissioner arrogated to himself a power and authority not granted to him, or to the Secretary, in the Color Additive Amendments, or otherwise, and not assigned to him by the Secretary, to establish a color licensing system, not only for the dyes and pigments, as authorized by Congress, but also for the finished cosmetic products, namely, lipsticks, rouge, eye makeup colors, hair dye products and related cosmetics intended for applying color to the human body, and thereby impose a requirement of premarketing clearance for the finished cosmetic products.

43. The Commissioner evidenced his intent to exceed the authority and power granted the Secretary by the Color Additive Amendments, and by regulation to assume the authority and power to require premarketing clearance of the finished cosmetic products, in his press release announcing the Color Regulations, wherein he stated, in substance and effect, that whereas "Previously only color of the coal tar type ingredients had been subject to the requirement for pre-marketing proof of safety," "Under the new regulations, FDA will require that an entire product—not just the color ingredient—be shown by the manufacturer to be safe before it is released for sale."

44. The Color Regulations, by defining the term "color additive" to include the finished cosmetic product and not merely the color ingredient, are not in accordance with law; are in excess of the statutory jurisdiction, authority and limitations of the defendants; are short of statutory right, are in derogation of the basic statutory purpose; are contrary to the statutory provisions on which they purport to be based; constitute an unwarranted and unlawful attempt by the Commissioner to establish premarketing clearance of the finished cosmetic products before such products may be sold and thereby seek to extend the scope of the Act [fol. L] and the color licensing system prescribed thereby to a major segment of the cosmetic industry to which Congress determined premarketing clearance should not apply,

and seek to obtain by regulation power and authority which Congress has refrained from granting by statute; expand the scope and application of a criminal and forfeiture statute and subject to criminal and forfeiture penalties matters which Congress did not provide should be subject thereto; and are illegal, void and of no effect.

Hardship Imposed on Plaintiffs by Such Definition of Color Additives to Include Finished Cosmetic Products.

45. Compliance with the unauthorized and illegal Color Regulations by the plaintiff companies is an extremely burdensome and costly task. The Color Regulations, by their expanded and unauthorized definition of a "color additive" to include the finished cosmetic product, among other things, require the plaintiff companies to petition the Commissioner for the listing of each finished cosmetic product made or sold by the plaintiff companies and to obtain certification or exemption from certification of batches of the finished cosmetic product. The petition for such listing requires that there be set forth the chemical identity and composition of the finished cosmetic product, its physical, chemical and biological properties, and specifications describing its components. Since the plaintiff companies purchase many of the ingredients of the finished cosmetic products from other manufacturers, such information is not within their knowledge or available to them. Such petition for listing also requires the performance of costly chemical and physical tests, and a description of the methods used in, and the facilities and controls used for, the production of the finished cosmetic product to be listed.

46. Compliance with the Color Regulations would require the plaintiff companies to change established business practices, seriously curtail the launching and market testing of proposed new finished cosmetic products, and cause major and costly disruption of their businesses. Such compliance with the Color Regulations will also require plaintiff companies in effect to disclose and make available to others

secret ingredients developed by them, which constitute a vital factor in the success of their businesses and a valuable property right, will permit appropriation by others of such secret ingredients and will discourage research and developmental work for the improvement and development of cosmetic products.

47. Each petition for listing must be accompanied by a \$2,600 fee, and a separate listing appears to be required for each product and for each shade of each product. Also, unless exempted from certification substantial certification fees must be paid with respect to each batch of the finished cosmetic product required to be certified. (28 Fed. Reg. 6439, 6448, §8.50). Included among the plaintiffs are companies known as private brand manufacturers which make finished cosmetic products for other cosmetic companies to be sold by them under their respective trademarks, trade names or other labels. Such private brand manufacturers make hundreds of separate formulae covered by the unauthorized expanded definition of the term "color additive", and the cost to them of compliance with the color licensing system, as unlawfully applied to their products, would amount to many millions of dollars and would destroy their businesses. The fees prescribed by the Color Regulations [fol. M] for listing and certification, when applied to the requirements applicable to each finished cosmetic product by reason of the unauthorized expanded definition of the term "color additive", are confiscatory and constitute an unlawful and unauthorized taking of property, and an illegal and discriminatory tax on a single industry, imposed by an administrative agency without statutory authority.

48. The Association acts in behalf of the plaintiff companies and its other members in seeking to clarify the scientific investigations and pharmacological and toxicological tests which FDA may regard as sufficient to accomplish required listing and certification or exemption from certification, in making contracts with consulting laboratories for such investigations and tests, and otherwise acts for the

plaintiff companies and its other members in respect of the application of the Color Regulations to their products and the efforts of its members to understand the Color Regulations and to comply therewith. The Association is recognized by the FDA as the representative of all the plaintiff companies and other cosmetic manufacturers with respect to various aspects of their compliance with the color licensing system. By reason of its activities and functions with respect to the color licensing system and the Color Regulations, the Association is affected by such Regulations.

49. The Act prescribes criminal penalties, including imprisonment and fine, and also authorizes multiple seizures and condemnation of foods, drugs and cosmetics and injunction proceedings for noncompliance with provisions of the Act and regulations thereunder.

50. The Color Regulations are formal and final regulations, are self-executing and written in mandatory terms and impose obligations upon the plaintiff companies. The adoption and promulgation of the Color Regulations impose a duty upon the defendants to require plaintiff companies to comply with them, in accordance with their terms. The defendants have determined to require compliance with the Color Regulations, in accordance with their terms, and have so advised the plaintiffs and all other persons manufacturing and selling cosmetics, and there is an actual and immediate threat that such compliance will be required of the plaintiff companies, and that the Color Regulations will be enforced, in accordance with their terms. The effect of the Color Regulations, unless this Court enters a judgment declaring that certain of their provisions referred to in this complaint are unwarranted, unauthorized and unlawful, is to require the plaintiff companies, in order to avoid criminal prosecution, proceedings for the seizure, condemnation and forfeiture of their products affected thereby and injunctive proceedings, to comply with the Color Regulations, with the tremendous expense and other burdens entailed in such compliance, as hereinabove alleged, or to fail to

comply with the Color Regulations, in so far as they exceed the statutory authority of the defendants and are illegal, and thereby incur the risk of the institution of one or more of such proceedings. The business of the plaintiff companies is a highly competitive one, and many millions of dollars are expended each year in advertising their products and in establishing and maintaining consumer confidence in and acceptance of their products, and consumer confidence in the reputation and integrity of the plaintiff companies. The mere institution of any of the foregoing proceedings against any of the plaintiff companies, or any of their products, regardless of the merits or eventual outcome of such proceedings, will have a serious, substantial and adverse effect on the business of the company involved, since the consumer would regard institution of any such [fol. N] proceeding as indicating lack of safety of the cosmetic involved, and the reputation and integrity of the manufacturer of such cosmetic, and the good will associated with its name, would be forthwith adversely affected, with serious and costly consequences to its business. The consequences of a successful criminal or seizure proceeding are additionally severe and could result in a fine, imprisonment, or both, and condemnation and forfeiture of cosmetics having substantial value. The adoption and promulgation of the Color Regulations and the application thereof to the plaintiff companies, and to their businesses, is an immediate and real one, and has an immediate and substantial effect upon the conduct of the plaintiffs, will cause them great and irreparable damage and injury and will substantially and adversely affect their business, and each of the plaintiffs has a substantial, immediate and real interest in the issue of the validity or invalidity of the Color Regulations, in the respects alleged in this complaint, and there exists between the parties an actual controversy, justiciable in character, as to such validity or invalidity of the Color Regulations.

51. More particularly, there exists between the parties an actual controversy, justiciable in character, as to whether

the plaintiff companies may lawfully, without subjecting themselves to criminal prosecution, seizure, condemnation and forfeiture of their products and injunctive actions, continue to manufacture and sell the finished cosmetic products without obtaining therefor premarketing clearance by the Commissioner, and without complying with the requirements of the color licensing system with respect to the entire product, even though the color additive or color ingredient has been pretested, listed and certified or otherwise is in full compliance with the color licensing system. The defendants, through the Color Regulations, in press releases and elsewhere, have taken the position that even though the color ingredient or color additive in the finished cosmetic product has been pretested, listed and certified or has been exempted from certification, the finished cosmetic product may not be sold unless it has received premarketing clearance, and has also complied with the pretesting, listing and certification, or exemption from certification, requirements of the color licensing system. The controversy between the parties under this count of the complaint turns upon the legal validity of the Color Regulations in such respect, which Regulations operate to impose the burden, hardship and irreparable damage and injury upon the plaintiff companies hereinabove alleged.

52. If the statutory definition of a color additive can be expanded by the Commissioner to include the finished cosmetic product, then, in as much as none of such products has been listed in any regulation and the two and one-half year period for "deemed" provisional listings, as described in paragraph 31, expired on January 12, 1963, all such products manufactured and sold by the plaintiff companies or by other cosmetic manufacturers at least since June 22, 1963, the date the Color Regulations were promulgated, would automatically be deemed unsafe and adulterated, with the consequence that such products, and the plaintiff companies, may now face the penalties imposed by the Act for the sale of adulterated cosmetic products. Also, on the

basis of such expansion by the Commissioner of the statutory definition of a color additive to include the finished cosmetic product, no new lipstick, rouge, eye makeup color, hair dye product or other new cosmetic intended for coloring the human body could be manufactured and sold without the premarketing clearance prescribed by the Commissioner, and all such new cosmetic products would also automatically be deemed unsafe and adulterated. The plaintiff companies require a declaration of whether their action in [fol. O] manufacturing and selling, and in continuing to manufacture and sell, the finished cosmetic products without having obtained premarketing clearance is now in violation of the Act, and automatically causes all such products to be deemed unsafe and adulterated.

53. Plaintiffs have no prompt, adequate and effective remedy at law, and this action is the only means available to them for the protection of their rights, and for protection against the immediate, real, substantial and irreparable damage and injury which the plaintiff companies face, as hereinabove alleged.

SECOND COUNT

54. The statements in paragraphs 1 to 39, inclusive, 45 to 50, inclusive, and 53, are adopted by reference.

Unauthorized and Illegal Application of the Color Licensing System to Diluents and the Classification of All Non-Color Ingredients as Diluents.

55. Dyes and pigments, as pure colors, have a strength in excess of that required to impart color to foods, drugs or cosmetics, and must, if utilized for such purpose, be diluted by an inert substance. Such inert substance used to dilute the color and diminish the strength of a dye or pigment is known in the color, food, drug and cosmetic industries as, and is herein called, "the diluent." The color manufacturer may sell the dye or pigment to the plaintiff companies as

a pure color or in a diluent which dilutes and diminishes its strength.

56. A dye or pigment, as a color additive, is also used to impart color to finished cosmetic products which do not have the purpose of applying color to the human body, such as perfumes, toilet water and colognes, bath salts, deodorants, and the like. All cosmetics which contain a dye or pigment added for the purpose of applying color to the human body or of imparting color to the cosmetic are in this count at times called the "finished cosmetic products."

57. The finished cosmetic products contain (a) a dye or pigment, (b) a diluent as defined in paragraph 55 and (c) a number of other ingredients (herein called the "other ingredients") intended for a variety of other purposes. The other ingredients are neither color additives nor diluents, and are not regarded as such in the color, food, drug or cosmetic industries. The other ingredients are purchased by the plaintiff companies from a variety of other manufacturers.

58. The Color Regulations initially gave the term "color additive" the same definition contained in the Act, as quoted in paragraph 24 hereof, namely, as meaning colors derived from natural sources and all synthetic dyes and pigments, instead of being limited to coal-tar colors, but then expanded the definition of the term by the following additional provision: "This includes all diluents" (§8.1(f)).

59. The Color Regulations define a "diluent" as follows (§8.1(m)):

"(m) The term 'diluent' means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. [fol. P] The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for ex-

ample sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body."

60. The term "color additive", as defined by Congress in the Color Additive Amendments, and as used in the color industry and in the food, drug and cosmetic industries for over fifty years, means the ingredient in the food, drug or cosmetic which imparts color thereto, namely, the dye or pigment, whether synthetic or natural, and does not mean the diluent or the other ingredients. All the color additives, as such term is defined by the Color Additive Amendments, used by each of the plaintiff companies in the finished cosmetic products are listed in currently outstanding provisional regulations promulgated by the Commissioner. The Color Additive Amendments provide for the listing of "color additives for use in or on cosmetics" (Section 706(b)(1)), and make it clear that the requirement for listing does not apply to diluents, by providing only "for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b)" (Section 706 (c)). The other ingredients are not listed in any currently outstanding regulation within the meaning of Section 706(a) of the Act, and the manufacture, sale and distribution by the plaintiff companies of finished cosmetic products containing the other ingredients constitute, according to the effect of the definition of "color additive" contained in the Color Regulations, an adulteration within the meaning of Section 601(e) of the Act.

61. By this expedient of expanding the meaning of the term "color additive" and by defining it to include diluents, and by defining diluents to mean all or substantially all the other ingredients, the Commissioner arrogated to himself a power and authority not granted to him, or to the Secretary, in the Color Additive Amendments, or otherwise, and not assigned to him by the Secretary, to establish a color licensing system, not only for the dyes and pigments, as

authorized by Congress, but also for all the other ingredients, and thereby apply to the other ingredients a requirement of advance approval or clearance which the Act limits to the color ingredient only.

62. The Color Regulations, by defining the term "color additive" to include diluents and not merely the color ingredient, and by defining diluents to mean all or substantially all the other ingredients, are not in accordance with law; are in excess of the statutory jurisdiction, authority and limitations of the defendants; are short of statutory right; are in derogation of the basic statutory purpose; are contrary to the statutory provisions on which they purport to be based; constitute an unwarranted and unlawful attempt by the Commissioner to establish premarketing clearance of all or substantially all the other ingredients before the finished cosmetic product may be sold, and thereby seek to extend the scope of the Act and the color licensing system prescribed thereby to the various industries which manufacture and sell the other ingredients, and seek to obtain by regulation power and authority which Congress has refrained from granting by statute; expand the scope and application of a criminal and forfeiture statute and subject to criminal and forfeiture penalties matters which Congress did not provide should be subject thereto; and are illegal, void and of no effect.

[fol. Q]

Hardship Imposed on Plaintiffs by Such Application of the Color Licensing System to Non-color Ingredients

63. The hardship, burden and expense of compliance with the unauthorized and illegal Color Regulations, and the unauthorized and illegal application of the color licensing system to all or substantially all the other ingredients of the finished cosmetic products, and the consequences thereof, are substantially as alleged in paragraphs 45 to 47, inclusive, and 50.

64. Compliance with the unauthorized and illegal Color Regulations, as they purport to be applicable to all or substantially all the other ingredients of the finished cosmetic products, in such an extremely burdensome and costly task and is so onerous that manufacturers or vendors of the other ingredients are unwilling to undertake the burden and expense involved, so that the plaintiff companies must either assume such burden and expense or be unable to use the other ingredients necessary to the finished cosmetic products.

65. There exists between the parties an actual controversy, justiciable in character, as to whether the plaintiff companies may lawfully, without subjecting themselves to criminal prosecution, seizure, condemnation and forfeiture of their products and injunctive actions, continue to manufacture and sell the finished cosmetic products without obtaining premarketing clearance by the Commissioner for the other ingredients, and without complying with the requirements of the color licensing system with respect to the other ingredients, even though the color additive or color ingredient has been pretested, listed and certified or otherwise is in full compliance with the color licensing system. The defendants, through the Color Regulations, and elsewhere, have taken the position that even though the color ingredient or color additive in the finished cosmetic product has been pretested, listed and certified or has been exempted from certification, the finished cosmetic product may not be sold unless the other ingredients therein have also complied with the pretesting, listing and certification, or exemption from certification, requirements of the color licensing system and have received premarketing clearance. The controversy between the parties under this count of the complaint turns upon the legal validity of the Color Regulations in such respect, which Regulations operate to impose the burden, hardship and irreparable damage and injury upon the plaintiff companies hereinabove alleged.

66. If the statutory definition of a color additive can be expanded by the Commissioner to include diluents, which he defines as meaning all or substantially all the other ingredients, then, in as much as none of such other ingredients has been listed in any regulation and the two and one-half year period for "deemed" provisional listings, as described in paragraph 31, expired on January 12, 1963, all the finished cosmetic products manufactured and sold by the plaintiff companies or by other cosmetic manufacturers, at least since June 22, 1963, the date the Color Regulations were promulgated, which contain such other ingredients, would automatically be deemed unsafe and adulterated, with the consequence that such products, and the plaintiff companies, now face the penalties imposed by the Act for the sale of adulterated cosmetic products. Also, on the basis of such expansion by the Commissioner of the statutory definition of a color additive to include diluents, so defined as meaning all or substantially all the other ingredients, no new cosmetic product which contains such other ingredients could be manufactured and sold without the premarketing clearance prescribed by the Commissioner, and all such new cosmetic products would also automatically be deemed unsafe and adulterated. The plaintiff companies require a declaration of whether their action in manufacturing and selling, and in continuing to manufacture and sell, the finished cosmetic products without having complied with the color licensing system, as applied by the Commissioner to the other ingredients, or without having obtained premarketing clearance for the other ingredients, is now in violation of the Act, and automatically causes all such products to be deemed unsafe and adulterated.

THIRD COUNT

67. The statements in paragraphs 1 to 39, inclusive, 45 to 50, inclusive, 53, 55, 58, 59 and 64, are adopted by reference.

Unauthorized and Illegal Application of the Act, the Color Regulations, Premarketing Clearance and the Color Licensing System to Hair Dyes.

68. Various of the plaintiff companies are engaged in the manufacture, distribution and sale in interstate commerce of finished cosmetic products designed for the purpose of coloring the hair, including products known as color shampoos, color rinses and color tints (herein at times called "hair dye products"). Hair dye products contain color additives, as defined in Section 201(t) of the Act. The color additives which are primarily used in hair dye products are coal-tar colors, as described in paragraph 7, and all or substantially all hair dye products manufactured or sold by plaintiff companies contain coal-tar colors. None of such hair dye products consists solely of a coal-tar color or dye, but all such products also contain, in addition to diluents, as defined in paragraph 55, other ingredients, such as wetting agents, hair conditioners, emulsifiers, shampoos and similar ingredients which increase the effectiveness of the product's hair coloring properties or improve the condition of the hair (herein called the "other ingredients").

69. The 1938 Act specifically exempted coal-tar hair dyes, other than eyelash and eyebrow dyes, from the provisions of Section 601(a) and (e) if their label and labeling contained a "caution" and directions for testing for possible skin irritation, known as patch-testing. Such Section provided:

"SEC. 601. A cosmetic shall be deemed to be adulterated—

"(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed

thereon: 'Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness', and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term 'hair dye' shall not include eyelash dyes or eyebrow dyes.

[fol. 5] "(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604."

70. Thus, when Congress enacted the 1938 Act to include cosmetics, it determined that the public interest was best served by exempting coal-tar hair dyes from Section 601(a) and from the color licensing system, and by requiring such cautionary statement and adequate directions for preliminary testing.

71. The Commissioner issued regulations under the 1938 Act, which were in effect at the time of the enactment of the Color Additive Amendments, and which defined the term "coal-tar hair dye" used in Section 601(a) of the 1938 Act as including "all articles containing any coal-tar color or intermediate which color or intermediate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual" (21 CFR 1.200). Such regulations were in compliance with and effectuated the statutory exemption for properly labeled hair dye products.

72. Since 1938, the FDA has consistently recognized that such statutory hair dye exemption applies to all hair dye

products containing a coal-tar color or intermediate, and has also consistently recognized that color shampoos, color rinses and color tints are terms used in the cosmetic industry to designate hair dye products which, though serving a dual purpose, are coal-tar hair dyes, and that such dual purpose products, being articles which when applied to the hair alter its color, were within such statutory hair dye exemption if they contained the prescribed cautionary label.

73. FDA officials subsequently regarded such specific statutory exemption for hair dye products as a "loophole" in the law, and the FDA has from time to time sponsored legislation designed to amend the Act to repeal such exemption.

74. The Color Additive Amendments did not change such statutory exemption for hair dyes but on the contrary emphasized the existence and continuance of the hair dye exemption by adding a new Section 602(e) "relating to the circumstances under which cosmetics shall be deemed to be misbranded," which provides that said Section 602(e) shall not apply to "color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of Section 601(a))."

75. The Commissioner, having been unable to obtain repeal of the statutory exemption for hair dyes, has sought by the Color Regulations to change and limit such exemption. Contrary to the language of the Act and its long-standing administration, the Color Regulations (Section 8.1 (f) (u)), in substance and effect and as interpreted by the FDA, narrow and limit the statutory exemption to apply only to the specific coal-tar color ingredients in hair dye products, and then only in so far as such ingredients are specifically covered by the prescribed cautionary label.

76. By such provision of the Color Regulations, which has changed and limited the statutory definition of "hair dye" to certain coal-tar color ingredients in hair dye prod-

ucts, and by the provisions of the Color Regulations quoted in paragraphs 40, 58 and 59 hereof, which changed the statutory definitions of a "color additive" to include all finished cosmetic products intended for coloring the human body, and also diluents, and which defined diluents as meaning all or substantially all the ingredients in the finished cosmetic product, the FDA, by the Color Regulations, seeks substantially to change and limit the statutory exemption for hair dyes, as follows:

(a) By applying the exemption of Section 601(a) only to certain coal-tar color ingredients in hair dye products, rather than to the entire product as had previously been the case; and

(b) By subjecting hair dye products, including the above referred to dual purpose products, and the other ingredients of hair dye products, to premarketing clearance and to the color licensing system.

77. To give effect to such attempt to limit the statutory exemption of hair dyes, the Commissioner, by regulation published in the Federal Register on October 3, 1963 (28 Fed. Reg. 10638), deleted the definition of hair dyes contained in Section 1.200 of said regulations referred to in paragraph 71, "the material therein having been superseded by §8.1(u)" of the Color Regulations.

78. By so limiting the hair dye exemption in the Act, the Commissioner arrogated to himself a power and authority not granted to him, or to the Secretary, in the Color Additive Amendment, or otherwise, and not assigned to him by the Secretary, and has thereby imposed a requirement of premarketing clearance and the color licensing system for such products, notwithstanding such specific statutory exemption.

79. The Commissioner evidenced his intent to exceed the authority and power granted the Secretary by the

Color Additive Amendments, and by regulation to assume the authority and power to apply the Color Regulations and the color licensing system to hair dye products exempted by the Act, and also to apply premarketing clearance to such hair dye products, in his press release, dated June 22, 1963, announcing the Color Regulations, wherein he stated, in substance and effect, that the hair dye exemption in the Act offered insufficient protection and that "the purpose of the new regulation is to close this gap," and that "Hair dyes that do not cause a reaction with the patch test must now be demonstrated to be safe before they can be marketed", and again in his press release, dated October 3, 1963, announcing deletion of the definition of hair dyes contained in Section 1.200 of said regulations referred to in paragraph 71, wherein he described the Color Regulations as "limiting the exemption for hair dyes under the Federal Food, Drug, and Cosmetic Act."

80. The Color Regulations, by limiting the statutory exemption of hair dyes and by extending the Act, the Color Regulations and the color licensing system to hair dye products, and in seeking to apply premarketing clearance to hair dye products, are not in accordance with law; are in excess of the statutory jurisdiction, authority and limitations of the defendants; are short of statutory right; are in derogation of the basic statutory purpose; are contrary to the statutory provisions on which they purport to be based; constitute an unwarranted and unlawful attempt by the Commissioner to apply the Act, the Color Regulations and the color licensing system to products which Congress provided should be exempt, and to seek to obtain by regulation power and authority which Congress has refrained from granting by statute; expand the scope and [fol. U] application of a criminal and forfeiture statute and subject to criminal and forfeiture penalties matters which Congress did not provide should be subject thereto; and are illegal, void and of no effect.

**Hardship Imposed on Plaintiffs by the Unauthorized
and Illegal Regulations Applicable to Exempt
Hair Dye Products.**

81. Various of the plaintiff companies manufacture and distribute hair dye products which are specifically exempt from the provisions of Sections 601(a) and 601(e) of the Act, but which the Color Regulations now purport to bring within the scope of such provisions, the Color Regulations and the color licensing system, and to which the Color Regulations now purport to apply a requirement of pre-marketing clearance not authorized by the Act. The hardship, burden and expense of compliance with the unauthorized and illegal Color Regulations, and the unauthorized and illegal application of the Act, the Color Regulations and the color licensing system to hair dye products exempted by the Act, and the consequences thereof, are substantially as alleged in paragraphs 45 to 47, inclusive, and 50.

82. There exists between the parties an actual controversy, justiciable in character, as to whether the plaintiff companies may lawfully, without subjecting themselves to criminal prosecution, seizure, condemnation and forfeiture of their products and injunctive actions, continue to manufacture and sell hair dye products without obtaining pre-marketing clearance by the Commissioner for the finished product, and for the other ingredients, and without complying with the requirements of the color licensing system with respect to the finished product and the other ingredients, and whether the plaintiff companies must regard the statutory exemption granted to hair dyes under Section 601(a) of the Act as repealed. The defendants, through the Color Regulations and elsewhere, have taken the position that notwithstanding the statutory exemption of hair dyes from Section 601(a) and (e), the defendants can impose substantial limitations on such exemption, and can also impose a requirement for premarketing clearance of hair dye products, and that such products may not be sold,

unless such products, and the other ingredients therein, have received premarketing clearance and have complied with the pretesting, listing and certification requirements of the color licensing system. The controversy between the parties under this count of the complaint turns upon the legal validity of the Color Regulations in such respect, which Regulations operate to impose the burden, hardship and irreparable damage and injury upon the plaintiff companies hereinabove alleged.

[fol. V]

✓ FOURTH COUNT

83. The statements in paragraphs 1 to 4, inclusive, and 53, are adopted by reference.

Unauthorized and Illegal Provisions of the Regulations as to Access to Processes and Formulae.

84. Section 704 of the Act, entitled "Factory Inspection", provides that designees of the Secretary may enter any factory, warehouse, or establishment in which food, drugs, devices or cosmetics are manufactured, processed, packed or held, and inspect such factory, warehouse, establishment and "all pertinent equipment, finished and unfinished materials; containers and labeling therein."

85. On October 10, 1962 (76 Stat. 792), the Act was amended to include special and additional inspection provisions, applicable to prescription drugs only, which provide that "the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded" are being manufactured, processed, packed, transported or held. The Act further provides that its special inspection provisions for prescription drugs do not apply to various types of data, such as financial, sales, pricing and research data, which are of a type normally regarded as confidential.

86. Severe penalties are prescribed by the Act for refusal to permit inspection, as authorized by Section 704, including imprisonment and fine, and injunction proceedings.

87. The legislative history of the "Factory Inspection" amendment shows that the authorized inspection power was limited, and that Congress did not intend to authorize inspection or require disclosure of records, processes or formulae of cosmetic manufacturers, or any other persons, except for said special provisions applicable to prescription drugs only.

88. The Color Regulations (§8.28(a)) provide that certification service may be suspended if a person has:

"(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived."

89. The term "color additive" is defined in the Color Regulations to include lipstick, rouge, eye makeup colors and other finished cosmetic products, and also diluents (§8.1(f)), and diluents are defined in the Color Regulations in effect as including all or substantially all the other ingredients contained in finished cosmetic products which contain a color (§8.1(m)).

90. The Commissioner has, by such provisions of the Color Regulations, in effect expanded the inspection power and authority, as delineated in Section 704 of the Act, so as to authorize inspection, access to and disclosure of all processes and formulae of finished cosmetic products which [fol. W] contain a color, even though the Act specifically limits the inspection of processes to prescription drugs, and nowhere authorizes inspection of, access to or disclosure of formulae, and the Commissioner has thereby arrogated

to himself a power and authority of inspection and access not granted to him, or to the Secretary, in the Act, in the Color Additive Amendments, or otherwise, and not assigned to him by the Secretary.

91. The Commissioner evidenced his intent to exceed the authority and power granted the Secretary by the Act and by the Color Additive Amendments, and by regulation to assume authority and power with respect to factory inspection and the right to obtain access to, and inspection and disclosure of, all "processes, and formulae" contrary to the authority granted by Congress, in his press release announcing the Color Regulations, wherein he stated:

"The regulations provide that FDA may refuse to certify a color additive—and thus in effect ban it from the market—if the manufacturer refuses FDA inspectors access to manufacturing facilities, processes, and formulas involved in the manufacture of the additive."

92. The Color Regulations, in so far as they purport to empower the Commissioner to obtain access to all processes and formulae involved in the manufacture of color additives, as such term is defined in the Color Regulations, at the penalty to the non-compliant manufacturer of banning his product from the market, are not in accordance with law; are in excess of the statutory jurisdiction, authority and limitations of the defendants; are short of statutory right; are contrary to the statutory provisions on which they purport to be based; constitute an unwarranted and unlawful attempt by the Commissioner to extend his powers and authority with respect to factory inspection and access to matters as to which Congress determined such power and authority should not apply, and seek to obtain, through the device of banning the product from the market, power and authority which Congress has refrained from granting by statute; expand the scope and application of a criminal and forfeiture statute and subject to criminal and forfeiture

penalties matters which Congress did not provide should be subject thereto; and are illegal, void and of no effect.

93. Secrecy of processes and formulae for various cosmetic products is of vital importance to plaintiff companies, as cosmetic manufacturers, and to the successful continuance of their businesses, and plaintiff companies and other cosmetic manufacturers take careful and unusual precautions to preserve such secrecy and not to permit others to obtain knowledge of their processes and formulae.

94. There exists between the parties an actual controversy, justiciable in character, as to whether the defendants may under the Act, or under the Color Additive Amendments, obtain access to all processes and formulae involved in the manufacture of color additives, as defined in the Color Regulations, including finished cosmetic products, under the penalty of having such products banned from the market. The defendants, through the Color Regulations, in press releases and elsewhere, have taken the position that, even though the Act does not grant them access to such processes and formulae, they can in effect obtain such access by refusing certification with the effect of having products of the plaintiff companies banned from the market. The controversy between the parties under this count of the complaint turns upon the legal validity of the Color Regulations in such respect, which Regulations operate to impose a burden, hardship and irreparable damage and injury upon the plaintiff companies.

Wherefore, plaintiffs pray that this Court:

(1) Issue a judgment declaring that the following provisions of the Color Regulations are not in accordance with law, are in excess of the statutory jurisdiction, authority and limitations of the defendants, and contrary to the statutory provisions on which they purport to be based, and are null and void and of no effect:

(a) The provisions of Section 8.1(f) of the Color Regulations which define as color additives lipstick, rouge, eye makeup colors and related cosmetics intended for coloring the human body, and any other provisions of the Color Regulations which have or may have the effect of defining or treating a finished cosmetic product as a color additive;

(b) The provisions of Section 8.1(f) and (m) of the Color Regulations which define a color additive as including diluents, and which define the term diluent in effect as including all or substantially all the ingredients and components of finished cosmetic products whether or not used to dilute the color and diminish the strength of the dye or pigment;

(c) The provisions of Section 8.1(f) and (u) of the Color Regulations which limit the exemption of hair dyes contained in the Act, and which in effect cause the Act and the Color Regulations to be applied to hair dye products and to the ingredients thereof which are exempt from the provisions of Sections 601(a) and (e) of the Act; and

(d) The provisions of Section 8.28(a)(4) of the Color Regulations, which, by their operation and effect, expand the right of FDA employees with respect to factory inspection, and grant them access to all processes and formulae involved in the manufacture of finished cosmetic products.

(2) Issue a judgment declaring that the finished cosmetic products now being manufactured, distributed and sold by the plaintiff companies, which are intended for applying color to the human body, or which contain a dye or pigment which imparts color to such products, are not to be deemed in violation of Section 601(a) and (e) of the Act because such products have not received premarketing clearance by FDA, or because the ingredients of such products, other than the color ingredient, have not complied with the color licensing system.

(3) Issue a judgment declaring that hair dye products now being manufactured, distributed and sold by the plaintiff companies are not to be deemed in violation of Section 601(a) and (e) of the Act because such products have not received premarketing clearance by FDA, or because the ingredients of such products have not complied with the color licensing system.

(4) Enjoin and restrain the defendants, and all persons acting under their direction and authority, or in active concert or participation with them, from enforcing or causing [fol. Y] to be enforced, or from attempting to enforce or to cause to be enforced, by any administrative action or civil or criminal proceeding or otherwise, the provisions of the Color Regulations alleged herein to be in excess of the statutory authority granted to the Secretary under the Act and to be null and void and of no effect.

(5) Issue a preliminary injunction enjoining and restraining the defendants and said persons from enforcing or causing to be enforced, or from attempting to enforce or to cause to be enforced, by any administrative action or civil or criminal proceeding or otherwise, said provisions of the Color Regulations, and to preserve the status and rights pending conclusion of this action; and

(6) Grant such other or further necessary or proper relief as may be appropriate.

Dated: November 15, 1963.

Breed, Abbott & Morgan, By William L. Hanaway,
By Edward J. Ross, Members of the Firm, Attorneys for Plaintiffs, Office and Post Office Address:
1 Chase Manhattan Plaza, New York 5, New York.

[fol. Z]

[File endorsement omitted]

[fol. 1]

IN UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Docket No. 30261

STATEMENT UNDER RULE 15(b)

This is an interlocutory appeal pursuant to Title 28, United States Code, Section 1292(b) from an order of the [fol. 2] United States District Court for the Southern District of New York (Tyler, J.) entered on December 8, 1965 denying appellants' motion to dismiss the complaint and for summary judgment.

This action was commenced by the filing of the complaint on November 15, 1963. On March 3, 1964 defendants moved to dismiss the complaint and on April 10, 1964 plaintiffs cross-moved for summary judgment in their favor. Both motions were denied by Hon. Harold R. Tyler, Jr. in an opinion filed November 17, 1964, which opinion is reported at 235 F. Supp. 648.

Thereafter, on November 20, 1964, the case was assigned to Judge Tyler for all purposes. Defendants' answer was filed on January 5, 1965.

On December 6, 1965 defendants moved again to dismiss and for summary judgment on the grounds that the complaint failed to state a justiciable controversy and that this is an unconsented suit against the United States. Again Judge Tyler denied the motion but this time he certified the questions for immediate appeal. The order was entered on December 8, 1965 and the opinion on which it is based was filed on December 13, 1965.

Appellants applied to this Court on December 16, 1965 for leave to appeal, which application was granted on January 10, 1966. The notice of appeal was filed on January 11, 1966.

[fol. 3]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
63 Civ. 3349

THE TOILET GOODS ASSOCIATION, INC., et al., Plaintiffs,

—v.—

ANTHONY J. CELEBREZZE, Secretary of Health, Education
and Welfare, and GEORGE P. LARRICK, Commissioner of
Food and Drugs, Defendants.

NOTICE OF APPEAL—Filed January 11, 1966

Sirs:

Please Take Notice that defendants, Anthony J. Celebrezze, Secretary of Health, Education and Welfare, and George P. Larrick, Commissioner of Food and Drugs, hereby appeal to the United States Court of Appeals for the Second Circuit from the order entered herein by Honorable Harold R. Tyler, United States District Judge, Southern District of New York, on the 8th day of December, [fol. 4] 1965, denying defendants' motion to dismiss the complaint on the grounds that (a) the complaint fails to set forth a justiciable controversy and (b) this is an unconsented suit against the United States, and the defendants appeal from the whole and from each and every part of said order and from the memorandum decision heretofore filed herein on the 13th day of December 1965 on which the said order is based.

This is an appeal pursuant to Title 28, U.S. Code, Section 1292(b) for which leave has been granted by the United States Court of Appeals for the Second Circuit by order dated January 10, 1966.

Dated: New York, N.Y.
January 11, 1966

Yours, etc.

Robert M. Morgenthau, United States Attorney for
the Southern District of New York, Attorney for
Defendants.

By Arthur S. Olick, Assistant United States
Attorney. Office & Post Office Address: United
States Court House, Foley Square, New York,
N.Y. 10007 Tel.: 264-6319.

To: Messrs. Breed, Abbott & Morgan, 1 Chase Manhattan Plaza, New York 5, N.Y.

[fol. 5]

IN UNITED STATES DISTRICT COURT

ORDER DENYING MOTION TO DISMISS AND FOR SUMMARY
JUDGMENT AND CERTIFYING AN IMMEDIATE APPEAL—
December 8, 1965

Defendants, having moved for summary judgment dismissing the complaint pursuant to F.R. Civ. Procedure 56 and 28 U.S.C. § 2201, on the grounds that (a) the complaint fails to set forth a justiciable controversy and (b) this is an unconsented suit against the United States, or, alternatively, for an order pursuant to 28 U.S.C. § 1292 (b) certifying said issues for an interlocutory appeal; and

The said motion having come on to be heard before me on December 6, 1965, and Arthur S. Olick, Esq., Assistant United States Attorney, having appeared on behalf of the defendants, and Edward J. Ross, Esq., having appeared on behalf of the plaintiffs,

Now, Therefore, upon the pleadings herein, defendants' notice of motion, dated November 18, 1965, and the affidavits of Arthur S. Olick, sworn to, respectively, on

November 18, 1965, December 1, 1965 and December 6, 1965, in support of the motion for summary judgment, and the affidavits of Edward J. Ross, sworn to, respectively, November 23, 1965 and December 3, 1965, in opposition thereto, and upon all the prior proceedings herein and all the documents heretofore filed herein, and due deliberation having been had, and the Court having rendered its opinion on December 6, 1965, to be followed by a memo-[fol. 6]andum to be filed herein, in which this Court adhered to its prior decision, filed on November 17, 1964, it is hereby

Ordered, that defendants' motion for summary judgment dismissing the complaint on the grounds that the complaint fails to set forth a justiciable controversy and this is an unconsented suit against the United States is denied in all respects; and it is further

Ordered, that this Court is of the opinion that this order involves controlling questions of law as to which there is substantial ground for difference of opinion, and that an immediate appeal from this order may materially advance the ultimate termination of the litigation; and it is further

Ordered, that if defendants make timely application to the Court of Appeals for permission to appeal from this order, the proceedings in the District Court shall be stayed pending determination of such application or of the appeal, if it is allowed.

Dated: New York, New York
December 8, 1965.

Harold R. Tyler, Jr., U.S.D.J.

[fol. 7]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

63 Civ. 3349

OPINION DATED DECEMBER 10, 1965—

Filed December 13, 1965

Tyler, D.J.

Defendants (hereinafter collectively referred to as "FDA"), with the permission of this court, have made a renewed motion to dismiss the complaint and for summary judgment pursuant to F.R.C.P. 56 and 28 U.S.C. 2201 on the grounds that the complaint fails to set forth a justiciable controversy and that this is unconsented suit against the United States. In the alternative, defendants have moved for an order pursuant to the provisions of 28 U.S.C. 1292(b) certifying the aforesaid issues for an interlocutory appeal.

By way of background, the principal impetus for this renewed motion stems from recent opinions filed by the United States Courts of Appeals for the Third Circuit in *Abbott Laboratories v. Celebrezze, et al.*, — F.2d —, decided November 1, 1965, and for the District of Columbia in *The Danville Tobacco Association et al. v. Freeman*, — F.2d —, decided September 30, 1965. Both decisions, in general terms, were rulings that the district courts should have dismissed complaints for failure to state justiciable controversies where complainants were ostensibly challenging the meaning and validity of agency [fol. 8] regulations. Thus, FDA here asserts that the facts of the present case are substantially analogous to those in *Abbott* and *Danville Tobacco*, and that, therefore, the decision of this court filed on November 17, 1964 and determining, among other things, that the present case presents a justiciable controversy in a context not involving an unconsented suit against the United States, should be reconsidered and overturned.

The parties amply briefed the issues upon this renewed motion, and oral argument were heard on December 6, 1965. On December 8, 1965, this court filed an order denying the renewed motion of FDA for dismissal but certifying the questions presented for an interlocutory appeal. This memorandum is designed to sketch the principal reasons for this court's refusal to disturb its original determination filed approximately one year ago.

No useful purpose can be served here in replowing the same ground covered in the opinion of this court reported at 235 F. Supp. 648. Essentially, I do not agree with FDA's arguments that *Abbott* and *Danville Tobacco* present facts and circumstances opposite to the case at bar.*

[fol. 9] As already indicated in the earlier opinion of this court, FDA in the last analysis has consistently bottomed all of its arguments upon the technical proposition that the regulations here under attack are "interpretive" as opposed to "legislative".** This cornerstone contention of FDA, it seems to me, has several deficiencies. Preliminarily, it smacks of hypertechnicality; in the words of Chief Justice Stone, "the ultimate test of reviewability is not to be found in an over-refined technique. . .". *Columbia Broadcasting System, Inc. v. United States*, 316 U.S. 407, 425 (1942). More significant, this court has already found upon the allegations of the complaint in this case, that FDA has promulgated final regulations pursuant to the Color Additives Amendments of 1960 enacted by Congress as part of the Food, Drug and Cosmetics Act (74 Stat. 397, Public Law 86-618, 86th Cong., 2d Session, 21 U.S.C. 321[+] and 376) (hereinafter the "Act"); that there is raised by the parties a substantial issue as to whether or not four of

* Indeed, *Danville Tobacco* seems to me so obviously inapposite as to warrant no detailed discussion whatsoever. I suspect that FDA in part would agree because its papers and oral argument were principally keyed to *Abbott*, with little or no detailed discussion of *Danville Tobacco*.

** See discussion in 57 Yale L. J. 919, 928-9 (1948).

these final regulations significantly exceed the legislative mandate of the 1960 Amendments; and that irreparable harm would attach to plaintiffs unless these issues are resolved in this declaratory judgment action prior to piecemeal administrative litigation upon individual license applications. It is in the light of these findings that I reach my opinion that *Abbott*, and, of course, *Danville Tobacco*, are distinguishable from this case.

Granting *arguendo* that *Abbott Laboratories* is generally [fol. 10] more similar to the present controversy, it must be emphasized that there the applicable statutory provision* merely required that with respect to prescription drugs, the established or generic drug name be printed "prominently" on the label in type half as large as any brand or proprietary name. Presumably, this "prominently" requirement could be satisfied in a number of ways such as by means of a special label in large type-face, or by printing the generic name in bold red letters and the like. In its pertinent regulations, FDA in effect provided that the generic name must be shown "prominently" not only on labels but "each time" the trade name is used for any purpose, whether it be advertising, labelling or whatever. Perhaps understandably under these circumstances, the Court of Appeals ruled that the issue presented was one of interpretation of the regulations in question and, as such, not cognizable by the district court.

But the situation in this case is significantly different. Here the plaintiff contends that: (1) the 1960 Color Additive Amendments require merely pretesting, listing and certification for dyes, pigments and other color ingredients; (2) they do not change the statutory exemption for hair dyes; and (3) they do not grant FDA access to industry formulae for cosmetic products. But plaintiffs also allege that FDA has issued regulations, purportedly under the authority of the Color Additive Amendments, which would:

* Section 502(e)(1)(B) of the Act.

(1) require pretesting, listing and certification for finished [fol. 11] cosmetic products, including hair dyes, and, as well, for the non-color ingredients of finished cosmetics; (2) change and limit the statutory exemption for hair dyes; and (3) grant FDA inspectors access to cosmetic formulae. In short, the complaint contains significant allegations of administrative regulations which rather markedly depart from what preliminarily appears to be the plain legislative authority conferred by Congress in the 1960 Color Additives Amendments.* Thus it is that in my opinion this case presents a different issue of "reviewability" or "justiciability" than that before the court in *Abbott Laboratories*.** Upon the complaint allegations, this is not necessarily a case where, as FDA is prone to argue, the parties are simply bickering as to how the regulations are to be interpreted and applied. Rather, on the face of the pleadings, this is a case involving allegations of serious and significant excesses by an executive agency, through the device of final regulations, beyond the powers conferred by Congress upon the agency in the 1960 Amendments. Whether or not these claims are true presents, in my view, a justiciable controversy which is ripe for determination by a district court under the Declaratory Judgment Act. [fol. 12] In reaching the latter conclusion, I am not unaware of another argument of FDA which, though not novel, takes on special focus by virtue of certain discussion of the Court of Appeals in *Abbott Laboratories*. FDA urges as a principal argument against reviewability here that Congress has provided another and more efficacious remedy for aggrieved industry members. In substance, this is the remedy of judicial review by a Court of Appeals from individual orders of the FDA upon applications for

* For other possible distinguishing factors, see discussion of this court at 235 F. Supp. at pages 651-2.

** Moreover, even if it be said that this case is not distinguishable from *Abbott*, then I would disagree with the reasoning and ultimate result to date of the latter case.

licenses for cosmetics, all as set forth in subsection (f)(1-5) of Section 701 of the Act. Apparently, FDA obtains comfort from certain statements concerning this statutory method of review by the Court of Appeals at 8 and 9 of its slip opinion in *Abbott Laboratories*. But, as I see it, such is cold comfort indeed in view of the fact that the Court of Appeals in *Abbott Laboratories* at the threshold had determined that they were concerned with an interpretive as opposed to "legislative" regulations such as are alleged in the case at bar. Moreover, subsection (f)(6) of Section 701 of the Act underscores the Congressional intention that the special review of license proceedings by the Courts of Appeals "shall be in addition to and not in substitution for any other remedies provided by law." Finally, it is scarcely to be thought that judicial review limited to the traditional and narrow scope of whether or not the Commissioner's findings are supported by adequate evidence can supplant the other and broader form of remedy or review available under the Declaratory Judgment Act.

A brief, final paragraph may be in order respecting that part of this court's December 8, 1965 order certifying the [fol. 13] questions pursuant to 28 U.S.C. 1292(b). Aside and apart from the circumstance that plaintiffs have agreed to the FDA's request for certification, it is clear from a review of the general case law in this field that, notwithstanding my firmly held views on the issues here of justiciability and whether or not this is an unconsented suit against the sovereign, there is ample room for difference of opinion. Further to bespeak the obvious, a different view than mine would quickly terminate this litigation, which, though only commenced last year due to doubtless necessary delays in the regulation making process, involves subject matters passed upon by the Congress five years ago. Even if the reviewing court were to agree that this court has properly taken jurisdiction, it must be borne in mind that this case was ready to proceed to trial on December 6,

1965, the day when this renewed motion was argued—i.e. in the event of an unsuccessful interlocutory appeal, this case presumably can be resolved on the merits without undue additional delay.

H. R. Tyler, Jr., U.S.D.J.

December 10, 1965.

[fol. 68]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANSWER—January 4, 1965

Defendants, Anthony J. Celebrezze, Secretary of Health, Education and Welfare and George P. Larrick, Commissioner of Food and Drugs, by their attorney, Robert M. Morgenthau, United States Attorney for the Southern District of New York, for their answer herein:

1. Deny each and every allegation contained in Paragraph "1" of the Complaint except admit that regulations entitled "Part 8-Color Additives" were published in the Federal Register, June 22, 1963, 28 F. R. 6439.
2. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "2" of the Complaint except deny that the plaintiffs have any right to relief here in respect of and arising out of the same transaction and occurrence or that questions of law and fact common to all of them, will arise in this action.
3. Deny each and every allegation contained in Paragraph "3" of the Complaint except admit that the defendant, the Honorable Anthony J. Celebrezze, is, and was at the time the regulations in question were published, the Secretary of Health, Education and Welfare of the United States of America and that as such he was and is authorized by Section 701(a) of the Federal Food, Drug and

Cosmetic Act, 21 U.S.C. 371(a) to promulgate regulations [fol. 69] and, pursuant to Section 706(b) and (c) of said Act, 21 U.S.C. 376(b) and (c), to provide, by regulation, for the separate listing of color additives for use in food, drugs, and cosmetics and for the certification [or exemption from certification] of batches of color additives; and except that defendants further admit that the defendant, George P. Larrick, is, and was, on the date the regulations in question were published, Commissioner of Food and Drugs of the United States of America, responsible for the supervision and administration of the Food and Drug Administration, in which capacity he did sign and cause to be published the regulations of June 22, 1963, entitled "Part 8—Color Additives." For further answer to said paragraph, defendants state that the authority for the defendant, George P. Larrick, to so sign and publish such regulations is granted to him, in his capacity as Commissioner, by the Secretary of Health, Education, and Welfare, 25 F.R. 8625.

4. Deny each and every allegation contained in Paragraph "4" of the Complaint.

5. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "5" of the Complaint.

6. Deny each and every allegation contained in Paragraph "6" of the Complaint.

7. Deny each and every allegation contained in Paragraph "7" of the Complaint except admit that the synthetic colors most widely used in the food, drug and cosmetic [fol. 70] industries are chemical components which are, or could be, derived from coal-tar or coal-tar constituents.

8. Deny each and every allegation contained in Paragraph "8" of the Complaint except admit that coloring materials are manufactured by chemical and dye corporations who sell such products to food, drug, and cosmetic

manufacturers and to ingredient manufacturers serving the food, drug, and cosmetic industries.

9. Deny each and every allegation contained in Paragraph "9" of the Complaint except admit that the Secretary of Agriculture was charged with the administration of the Food and Drug Act of 1906; that the Act of 1906 did not specifically refer to cosmetics; that many color manufacturers submitted to the Department of Agriculture, pursuant to a voluntary program of certification, samples of some batches of coal-tar colors; and that, where such batches were found to be harmless, they were so certified by the Department of Agriculture.

10. Deny each and every allegation contained in Paragraph "10" of the Complaint except admit that the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, was enacted in 1938 and for the true terms and conditions thereof defendants shall refer to the official text upon the trial of this action.

11. Admit the allegations contained in Paragraphs "11", "12" and "13" of the Complaint except deny that the said quotations are complete.

[fol. 71] 12. Deny each and every allegation contained in Paragraph "14" of the Complaint and for the true terms and conditions of the said statute and regulations defendants shall refer to the official texts thereof on the trial of this action.

13. Deny each and every allegation contained in Paragraph "15" of the Complaint except admit that, pursuant to the 1938 Federal Food, Drug, and Cosmetic Act, 118 coal-tar colors were listed by the Food and Drug Administration; and except deny knowledge or information sufficient to form a belief with respect to whether or not such colors include substantially all the color additives which were added to and used in lipsticks, rouges, and nail polish enamels in excess of 95% of such cosmetics sold in the United States.

14. Deny each and every allegation contained in Paragraph "16" of the Complaint except admit that on December 15, 1958 the Supreme Court decided *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, the true terms and conditions of which are set forth in the official reports.

15. Deny each and every allegation contained in Paragraph "17" of the Complaint except admit that the then Secretary and the Commissioner of Food and Drugs initiated a review of all listed coal-tar colors as early as 1950, as well as a scientific study of several such colors, with the result that seven basic colors were removed from the harmless list and other colors were in the process of removal from such lists when the Color Additive Amendment was passed.

[fol. 72] 16. Deny each and every allegation contained in Paragraph "18" of the Complaint.

17. Deny each and every allegation contained in Paragraph "19" of the Complaint except admit that the Secretary of Health, Education, and Welfare did support a bill before Congress which would empower the Department of Health, Education, and Welfare to establish tolerance limitations and any other needed restrictions on the use of color additives in finished products, such limitations to be based upon the principle that any color additive must be safe for its intended use before its use should be permitted which support is fully set forth in the Hearings in H.R. 7624, 86th Cong., 2d Sess. (1960), pp. 15-32, 36-105, 495-538.

18. Admit the allegations contained in Paragraph "20" of the Complaint except deny that the said quotation constituted a complete statement of the emergency.

19. Deny each and every allegation contained in Paragraph "21" of the Complaint except admit that the 1938 Federal Food, Drug, and Cosmetic Act was limited to coal-tar colors, but assert that "coal-tar" colors were defined by an administrative regulation promulgated in 1939 as "articles (1) which are composed of or contain any sub-

stance derived from coal-tar, or any substance so related in its chemical structure to a constituent of coal-tar as to be capable of derivation from such constituent; and (2) when added or applied to a food, drug, or cosmetic or the human body or any part thereof, are capable (alone [fol. 73] or through reaction with other substances) of imparting color thereto."

20. Deny each and every allegation contained in Paragraph "22" of the Complaint except admit that the Department of Health, Education, and Welfare favored an expansion of the color additives legislation so that it would apply to all colors, not just coal-tar colors and their derivatives.

21. Admit the allegations of Paragraph "23" of the Complaint except deny that the said quotation is complete.

22. Deny each and every allegation contained in Paragraph "24" of the Complaint except admit the accuracy of the quotation of *Part of Section 201(t) of the Federal Food, Drug, and Cosmetic Act*.

23. Deny each and every allegation contained in Paragraph "25" of the Complaint except admit that these were two of the purposes of the new legislation, the paramount purpose of which was to provide an entirely new legal mechanism for applying the safe-for-use principle to "color additives" so as to allow the use of color additives which were themselves toxic, under tolerances and other use restrictions to be established in regulations, and to apply the new law both to the color additives themselves as ingredients and to any food or cosmetic which was or which bore or contained any unapproved color additive. See Sec. 402 (c), 601(e), 21 U.S.C. 342(c) and 361(e); H.R. Rep. 1761, 86th Cong., 2d Sess., and Hearings on H.R. 7624, 86th [fol. 74] Cong., 2d Sess.

24. Deny each and every allegation contained in Paragraph "26" of the Complaint except as hereinabove specifically admitted.

25. Deny each and every allegation contained in Paragraphs "27" through "32" of the Complaint except admit

the enactment of the statutes therein referred to and for the true terms and conditions thereof defendants shall refer to the official text upon the trial of this action.

Responding specifically to paragraph 27, the defendants assert that the safe-for-use principle is incorporated in Section 706(b), 21 U.S.C. 376(b); that defendants are directed to provide for the listing of color additives only to the extent that they will be safe when employed under the conditions authorized in regulations; that such regulations, to the extent deemed necessary by the Secretary to assure safe use, may prescribe the conditions of use (including, but not limited to, specifications as to the maximum quantities which may be used or permitted to remain in or on any articles, specifications as to the manner in which such additive may be added or used, and directions and labeling and packaging requirements for such additives), Sec. 706(b)(3); that the Secretary is directed to take into account specified relevant factors in determining likely safe use, which include use and exposure data, information on the cumulative effect of any such additive and any related substance on man or animal, appropriate safety factors, and the availability of any needed practicable methods of analysis for the [fol. 75] additive or for any substance formed in or on food, drugs, or cosmetics as a result of the use of any such additive, Sec. 706(b)(5)(A); that no color additive may be approved if it has a cancer-producing potential, Sec. 706(b)(5)(B); that no color additive may be listed if the proposed use would promote deception or result in adulteration or misbranding, Sec. 706(b)(6); that no tolerance may be established unless the amount tolerated will be safe and no tolerance shall be set at a level higher than necessary to achieve the intended effect, Sec. 706(b)(7); and that the Secretary may allocate color additives among foods, drugs, and cosmetics when this is necessary to achieve safety in use, Sec. 706(b)(8).

Replying specifically to paragraph 23, defendants admit that they are directed to provide separate lists for color additives for food, drug, and cosmetic use, and that they

are to provide for certification of batches of safe color additives, with safe diluents or without diluents, or to exempt color additives from batch certification when that is not necessary for the protection of the public health.

Replying specifically to paragraph 29, the defendants assert that the "adulteration" provisions are found in Sections 402(c), 501(a)(4), and 601(e) of the Federal Food, Drug, and Cosmetic Act.

Replying specifically to paragraph 30, defendants assert that color additives may not be listed for safe use unless the scientific data available supports that conclusion, that this may necessitate the accumulation of safety data at [fol. 76] some expense, and that provisional listing was authorized during the transitional period from the coal-tar certification system to the new safe-for-use listing and certification system.

Replying specifically to paragraph 31, the 1960 Amendments provided for certain color additives to be deemed provisionally listed during this transitional period.

Replying specifically to paragraph 32, defendants admit that the provisional listing and deemed provisional listings were to continue for 2½ years, with authority in the Secretary to extend these listings upon a finding that it was reasonably safe to do so while the scientific investigations were under way, and with equal authority to terminate forthwith any provisional listing or deemed provisional listing at any time when safety could no longer be reasonably assured.

26. Admit the allegations contained in Paragraph "33" of the Complaint except that for the true terms and conditions of the said regulations defendants shall refer to the official text thereof upon the trial of this action.

27. Deny each and every allegation contained in Paragraph "34" of the Complaint except admit that the color additives then provisionally listed by the Commissioner of Food and Drugs did not include finished cosmetic products and that temporary tolerances have been prescribed as an

interim measure under the transitional provisions of the law for a group of colors in lipstick [21 C.F.R. 8.503] until [fol. 77] the proof could be developed as to the safety of the lipsticks containing a group of coal-tar colors on the deemed-provisional list.

28. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "35" of the Complaint except admit that they have been advised informally about the alleged program of testing sponsored by the plaintiffs. Defendants allege affirmatively that no completed data has been submitted to them; that the defendants have not approved any color additives on the basis of such investigations; that on July 6, 1963, the defendants called upon interested persons for information about diluents, including safety data; that the last submission of information from the Toilet Goods Association was submitted with a letter dated November 20, 1964, giving the results of a questionnaire survey on the length of time certain non coal-tar colors had been used in cosmetics; and that as a result of the request for information about the use of diluents, some information has been offered by individual firms on about 60 diluents.

29. Deny each and every allegation contained in Paragraph "36" of the Complaint except admit that the two and one-half year period prescribed by the Color Additives Amendment, Sec. 203(a)(2)(A), expired on January 12, 1963 and that the closing date of colors provisionally listed was postponed under authority granted by Sec. 203(a)(2)(B), and that such provisionally listed colors constitute the class of colors which may be used in cosmetics pending the [fol. 78] issuance of permanent listings of color additives as safe for their intended uses.

30. Deny each and every allegation contained in Paragraphs "37" and "38" of the Complaint except admit the enactment of the said statute, for the true terms and conditions of which defendants shall refer to the official text upon the trial of this action.

31. Deny each and every allegation contained in Paragraphs "39" and "40" of the Complaint except admit the promulgation of the said regulations and for the true terms and conditions thereof defendants shall refer to the official text upon the trial of this action.

32. Deny each and every allegation contained in Paragraph "41" of the Complaint except admit that no color additive for cosmetic use has been listed in any current regulation published pursuant to Sec. 706(a) of the Federal Food, Drug, and Cosmetic Act; that all such color additives are on the provisional list at this time; that there is a temporary tolerance for certain coal-tar colors in lipstick; that other color cosmetics are using provisionally listed or deemed provisionally listed color components during the transitional period; that pending the outcome of this litigation, there has been no threat of enforcement against color cosmetics; and that as to finished commodities, the permanent listing regulation for food color additives include at least two articles which are finished food ingredients. §§8.301, 8.306.

33. Defendants deny each and every allegation contained [fol. 79] in Paragraph "42" of the Complaint.

34. Deny each and every allegation contained in Paragraph "43" of the Complaint except admit that the quotation appearing therein is an accurate quotation from a press release issued upon the publication of the Color Regulations in question.

35. Deny each and every allegation contained in Paragraph "44" of the Complaint.

36. Deny each and every allegation contained in Paragraph "45" except as hereinbefore specifically admitted.

37. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "46" of the Complaint except admit that requiring advance proof of safety for intended use will require plaintiff companies to reexamine established business

practices, and will have an impact on the launching and marketing of proposed new cosmetics.

38. Deny each and every allegation contained in Paragraph "47" of the Complaint except as hereinbefore specifically admitted and except that defendants deny knowledge or information sufficient to form a belief with respect to whether some of the plaintiffs are known as private brand manufacturers which make cosmetic products for other companies.

39. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained [fol. 80] in Paragraph "48" of the Complaint except deny that the Toilet Goods Association is affected by the said regulations.

40. Deny each and every allegation contained in Paragraphs "49" and "50" of the Complaint except as hereinbefore specifically admitted.

41. Deny each and every allegation contained in Paragraphs "51", "52" and "53" of the Complaint.

42. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "55" of the complaint, except admit they have certified both batches of pure coal-tar colors and coal-tar color mixtures for cosmetic use; that many pure dyes and pigments have such tinctorial strength that they must be diluted to serve as components of food, drugs, or cosmetics or as cosmetics; that diluents are used for this purpose; and that the diluents customarily used in coal-tar color mixtures were vehicles such as water, glycerine, alcohol, sugar, etc., which served to facilitate the use of the color in the food, drug, or cosmetic for which the color was intended.

43. Admit the allegations contained in Paragraph "56" of the Complaint.

44. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in

Paragraph "57" of the Complaint except admit that many [fol. 81] finished cosmetic products contain dyes, diluents, and other ingredients and that doubtless many such ingredients are purchased by the plaintiff companies from a variety of manufacturers.

45. Deny each and every allegation contained in Paragraph "58" of the Complaint except admit that the notice of proposed rule-making on the color additive regulations was published in the Federal Register on January 24, 1961, 26 F.R. 679, and that the rules were promulgated by an order published in the Federal Register on June 22, 1963, 28 F.R. 6439, and that for the true terms and conditions thereof defendants shall refer to the official texts upon the trial of this action.

46. Admit the allegations of Paragraph "59" of the Complaint.

47. Deny each and every allegation contained in Paragraphs "60", "61" and "62" of the Complaint.

48. In response to Paragraph "63" of the Complaint defendants repeat and reallege their responses to Paragraphs "45", "46", "47" and "50" of the Complaint as if here set forth at length.

49. Deny each and every allegation contained in Paragraphs "64", "65" and "66" of the Complaint.

50. Deny each and every allegation contained in Paragraph "68" of the Complaint except admit that many of the plaintiff companies are engaged in the manufacture, distribution, and sale in interstate commerce of finished cosmetic products which are used for coloring the hair; that [fol. 82] hair-dye products contain other ingredients than coal-tar color and dyes; that some hair dye products manufactured and sold by various of the plaintiff companies do not contain any coal-tar colors; that such products, such as tinting shampoos, do color the hair and such products do have potentials for harmful effects other than those caused by sensitization, including such reactions as cirrhosis of the liver or nephritis of the kidneys.

51. Deny each and every allegation contained in Paragraph "69" of the Complaint except admit the accuracy of the statutory quotation contained therein.

52. Deny each and every allegation contained in Paragraph "70" of the Complaint except admit the enactment of the said statute for the true terms and provisions of which defendants shall refer to the official text on the trial of this action.

53. Deny each and every allegation contained in Paragraphs "71" through "76" of the Complaint except admit that the Commissioner issued regulations under the 1938 Act; that the FDA has from time to time suggested legislation to amend the Act; that Section 602(e) was added to the Act by the Color Additive Amendments; and that for the true terms and provisions of such regulations and statutes defendants shall refer to the official texts thereof on the trial of this action.

54. Deny each and every allegation contained in Paragraphs "77" and "78" of the Complaint except admit that on October 3, 1963, there were published, at 28 F.R. 10638, [fol. 83] regulations which omitted the definition of hair dye previously published in other regulations.

55. Deny each and every allegation contained in Paragraph "79" of the Complaint except admit that defendant Larrick issued a press release dated June 22, 1963; stated that hair coloring products that did not cause a reaction with the patch test must now be demonstrated safe before they can be marketed; and that a press release was issued October 3, 1963; which contained the statements quoted in said Paragraph "79" of the Complaint.

56. Deny each and every allegation contained in Paragraph "80" of the Complaint.

57. In response to Paragraph "81" of the Complaint defendants repeat and reallege their responses to Paragraphs "45", "46", "47" and "50" of the Complaint as if

here set forth at length and otherwise deny each and every allegation contained in said Paragraph "81".

58. Deny each and every allegation contained in Paragraph "82" of the Complaint.

59. Admit each and every allegation contained in Paragraphs "84", "85" and "86" of the Complaint, except deny that the Act prescribes any mandatory penalty for refusal to permit factory inspection and allege that no precautions of cosmetic manufacturers have ever been recommended to the Department of Justice under this section of the statute.

60. Deny each and every allegation contained in Paragraph [fol. 84] graph "87" of the Complaint.

61. Deny each and every allegation contained in Paragraph "88" of the Complaint except admit the accuracy of the quotation contained therein.

62. Deny each and every allegation contained in Paragraph "89" of the Complaint except that the Color Regulations contain definitions of "color additive" and "dilutents" and for the true terms and provisions of such regulations, defendants will refer to the official text upon the trial of this action.

63. Deny each and every allegation contained in Paragraph "90" of the Complaint.

64. Deny each and every allegation contained in Paragraph "91" of the Complaint except admit that defendant Larriek, in a press release announcing the Color Regulations, made the statement attributed to him in the said Paragraph.

65. Deny each and every allegation contained in Paragraph "92" of the Complaint.

66. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "93" of the Complaint.

67. Deny each and every allegation contained in Paragraph "94" of the Complaint.

[fol. 85]

As and for a First Separate Defense Defendants Allege:

68. The Complaint fails to state a claim against these defendants upon which relief can be granted.

As and for a Second Separate Defense Defendants Allege:

69. This Court lacks jurisdiction over the subject matter.

As and for a Third Separate Defense Defendants Allege:

70. Plaintiffs have failed to join an indispensable party, to wit, the Attorney General of the United States.

As and for a Fourth Separate Defense Defendants Allege:

71. This is an unconsented suit against the United States and, therefore, the Court lacks jurisdiction over the person of the defendants.

As and for a Fifth Separate Defense Defendants Allege:

72. Plaintiff, The Toilet Association, Inc., has no standing to sue.

[fol. 86]

As and for a Sixth Separate Defense Defendants Allege:

73. As to 27 of the plaintiff corporations, incorporated in states other than the State of New York, venue is improperly laid in the Southern District of New York.

As and for a Seventh Separate Defense Defendants Allege:

74. The Complaint fails to allege a case of actual controversy within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201.

As and for an Eighth Separate Defense Defendants Allege:

75. The Regulations here at issue are, in all respects, in accordance with the provisions of the Federal Food,

[fol. 87] Drug and Cosmetic Act and in no way exceed any authority granted thereby.

Dated: New York, New York, January 4, 1965.

Robert M. Morgenthau, United States Attorney for the Southern District of New York, Attorneys for Defendants, By: Arthur S. Olick, Assistant U.S. Attorney, Office & P.O. Address: United States Courthouse, Foley Square, New York, New York, 10007, CO 7-7100, ext. 319.

To: Breed, Abbott & Morgan, Esqs., Attorneys for Plaintiffs, 1 Chase Manhattan Plaza, New York, New York, 10005.

[fol. 88]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

63 Civ. 3349

Breed, Abbott & Morgan, of New York, N.Y., Attorney for Plaintiff, William L. Hanaway, Esq., Edward J. Ross, Esq., and Stephen R. Lang, Esq., of Counsel.

Robert M. Morgenthau, United States Attorney, Attorney for Defendants, by Arthur S. Olick and Patricia A. Garfinkel, Assistant United States Attorneys, and William W. Goodrich, Assistant General Counsel for Food & Drugs, and William R. Pendergast, Esq., Attorney, United States Department of Health, Education & Welfare.

OPINION DATED NOVEMBER 16, 1964—Filed November 17, 1964.

TYLER, D.J.

Forty individuals and companies manufacturing, distributing, and selling cosmetics in interstate commerce and

an association of cosmetic manufacturers here seek a declaratory judgment [28 U.S.C. § 2201] as to the validity of certain provisions of regulations promulgated by the Commissioner of the Food and Drug Administration (FDA). These regulations were issued pursuant to the 1960 Color Additives Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-81.* More specifically, plaintiffs con-[fol. 89] tend that the challenged regulations exceed the authority vested in the FDA by the statute, as amended, and pray that the Court declare the regulations null and void and enjoin their enforcement.

Essentially, the 1960 Amendments expand the Act's provisions for the pretesting of coal tar colors to require the pretesting of all color additives, irrespective of their derivation. To this end, the term "color additive" is defined as "a dye, pigment, or other substance" which, "when added or supplied to a food, drug or cosmetic, or to the human body or any part thereof, is capable . . . of imparting color thereto." 21 U.S.C. § 321(t)(1). The Amendments further state that color additives shall be deemed "unsafe" within the meaning of the Act unless they conform to regulations for the listing of additives and for "the certification, with safe diluents or without diluents, of batches of color additives." 21 U.S.C. § 376.

To implement these Amendments, the Commissioner of the FDA issued the Color Additives Regulations, dated June 13, 1963.** 28 F.R. 6439, 21 C.F.R. §§ 8.1-8.6003. Those provisions of the regulations here challenged as in excess of the statutory authority on which they purport to be based are:

[fol. 90] (a) provisions of Section 8.1(f) which, it is claimed, may have the effect of defining a color additive

* The Amendments were enacted on July 12, 1960.

** Actually, 21 U.S.C. § 371(a) vests in the Secretary of the Department of Health, Education and Welfare the authority to promulgate Food & Drug Act regulations. Defendants' memoranda explain that the responsibility for their actual promulgation was delegated to the Commissioner.

as including finished cosmetic products, and consequently, of requiring the pre-testing of finished products;

(b) provisions of Sections 8.1(f) and (m) which define color additives as including all diluents and which, plaintiffs claim, may require the pre-testing, listing and certification of all ingredients of cosmetics containing a color additive mixture;

(c) provisions of Section 8.1(f) and (u) which are claimed to make nugatory any statutory exemption for hair dyes, 21 U.S.C. § 361(a) and (e); and

(d) provisions of Section 8.28(a)(4) which plaintiffs contend is an unwarranted grant of access by FDA investigators to all processes and formulae involved in the manufacture of cosmetics.

Defendants have moved for an order dismissing the complaint, and, alternatively, for an order "striking" certain portions of the complaint." *

I.

Defendants' principal contention on their motion to dismiss is that the complaint fails to state a case of actual controversy, as required by the Declaratory Judgment Act, 28 U.S.C. § 2201, particularly because of the absence of any [fol. 91] threatened or attempted enforcement of the regulations.

Although the Declaratory Judgment Act was never intended or construed to grant the federal courts license to render advisory opinions, threatened enforcement of a statute or administrative regulation is not a *sine qua non* for its review under the Act. See *Borchard, Declaratory Judgments* (2d ed., pp. 365-6). In *Columbia Broadcasting System, Inc. v. United States*, 316 U.S. 407, 417-18 (1942), FCC regulations provided that radio stations would have their licenses revoked if they entered into contracts with

* Defendants, however, have not specified which portions they wish stricken.

networks containing certain prohibited clauses. The court held the regulations to be reviewable because of their serious impact upon the radio network's ability to conduct its business and stated that, "If an administrative order has that effect it is reviewable and it does not cease to be so merely because it is not certain whether the Commission will institute proceedings to enforce the penalty incurred under its regulations for noncompliance."

Recently, in *Abbott Laboratories v. Celebrezze*, 228 F. Supp. 855 (D. Del. 1964), where drug manufacturers challenged FDA labeling regulations, Chief Judge Wright held, at page 861:

"Plaintiffs may have judicial review of interpretive regulations upon their promulgation without awaiting some ultimate enforcement. *Frozen Food Express v. United States*, 351 U.S. 40, 76 S. Ct. 569, 100 L.Ed. 910 (1956); *Federal Trade Commission v. Nash-Finch Company*, 110 U.S. App. D.C. 5, 288 F.2d 407. They [fol. 92] need not await an action which would only make the threat of harm more pressing."

Thus, while the threat of enforcement is often present in cases where the courts have taken jurisdiction and rendered a declaratory judgment on the validity of a challenged regulation or statute, the existence of such a threat merely serves as some evidence indicating the presence of an actual controversy and that the plaintiff stands to suffer "real, immediate and incalculable" harm. See concurring opinion of Mr. Justice Douglas, *Joint Anti-Fascist Refugee Committee v. McGrath*, 341 U.S. 123, 175 (1951).

In *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1940), the Supreme Court said that, "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

More specifically, as to the reviewability of administrative rulings, Chief Justice Stone said in *Columbia Broadcasting System, Inc. v. United States*, *supra*, at page 425:

"The ultimate test of reviewability is not to be found in an overrefined technique, but in the need of the review to protect from the irreparable injury threatened in the exceptional case of administrative rulings which attach legal consequences to action taken in advance of other hearings and adjudications that may [fol. 93] follow, the results of which the regulations purport to control."

This being the test, I find it difficult and indeed inappropriate, at least under the circumstances here presented, to resolve the issue of reviewability upon the technical distinction, pressed by defendants, between legislative and interpretive regulations. Parenthetically, I should add that I read no federal authority to precisely support the defendants' argument that the regulations here involved are "interpretive" as opposed to "legislative" and thus do not "approach a degree of finality such as would warrant access to the Courts". (See page 59 et seq. of the government's principal brief).*

In any event, for reasons to be discussed hereinafter, I conclude that in a substantial and practical business sense plaintiffs are threatened with irreparable injury by the obviously intended consequences of the challenged regulations, and that to resort to later piecemeal resolution of the controversy in the context of individual enforcement proceedings would be costly and inefficient, not only for the plaintiffs but as well for the public as represented by the defendants.

* In fairness to defendants, however, it must be said that some commentators and courts have discussed this distinction in theoretical terms. See Davis, *Administrative Rules—Interpretative, Legislative and Retroactive*, and cases therein cited. 57 Yale L. J. 919, 928-29 (1948).

The regulations force manufacturers to choose between [fol. 94] complying with them, at a cost that may prove to be prohibitive for some of the plaintiffs, or ignoring them at the risk of incurring the statutory penalties should the regulations later be held valid. And, as Chief Judge Wright recently observed in the *Abbott Laboratories* case, *supra*, at 862: "The declaratory judgment procedure is specifically suited for the determination of controversies where the plaintiffs must either comply with a contested regulation or continue their present course of conduct at their peril."

An affidavit submitted on behalf of one of the plaintiffs asserts that the cost of compliance to this plaintiff alone will be over \$50,000,000. While this amount is immediately suspect,* there can be little doubt but that the added recordskeeping and laboratory testing costs in themselves will be extremely burdensome for all of the plaintiffs.

Aside from such measurable out-of-pocket costs of compliance, it is not difficult to perceive that the impact of the regulations on plaintiffs' present methods of doing business will be substantial and will give rise almost certainly to potentially greater expenses. That the latter are "hidden expenses" in the sense that they are presently incalculable does not diminish their significance. For ex- [fol. 95] ample, in the area of research alone, plaintiffs' affidavits show that the provisions of the regulations dealing with listing and with access to all formulae and processes will have an immediate adverse effect upon further research and development of new products. The situation here, incidentally, contrasts sharply with the facts of *Helco v. McNutt*, 137 F.2d 681 (D.C. Cir. 1943), where the plaintiff sought a declaratory judgment on the validity of a simple advisory opinion of the FDA elicited in response to the plaintiff's inquiry whether or not its proposed busi-

* The affiant apparently confused § 8.50(c) of the regulations, which requires a *deposit* of \$2,600 for each listing application, with § 8.50(j), which establishes a *fee* of \$250 "for services in listing a diluent" for use in color additive mixtures.

ness venture would violate the Food and Drug Act. Rather, we are dealing with a case that more closely parallels *Wallace v. Currim*, 95 F.2d 856 (4th Cir. 1938), *aff'd.*, 306 U.S. 1 (1939). The court in that case held that the plaintiffs, tobacco warehousemen, could challenge the 1955 Tobacco Inspection Act in a declaratory judgment suit because of the Act's substantial interference with their businesses, notwithstanding the fact that the cost of compliance for each warehouseman would only be \$25 per marketing season.

Having established that a justiciable controversy exists, there are at least two compelling reasons for assuming jurisdiction and determining in this action the validity of the challenged regulations.

First, since a concern for consumer safety is ostensibly the principal motive underlying promulgation of the Color Additives Regulations, there is a strong public interest in an early determination of their validity. Four years have already elapsed since Congress enacted the statutory pro-[fol. 96] visions which the regulations seek to implement. Any further delay in determining whether or not the cosmetic industry need comply with the regulations will only serve to further frustrate Congress' purpose of providing the consuming public with protection against potentially harmful color additives.

Second, this action provides an opportunity to examine all four challenged regulatory provisions together within the context of a single plenary proceeding. Since these four provisions are interrelated as elements of a common plan of governmental regulation, there is a distinct advantage in reviewing them together. Moreover, since the regulations raise complicated and technical issues which will require expert testimony to resolve—undoubtedly from many of the same witnesses—there is a practical advantage for the litigants as well as for the court in having this testimony brought forth in a single action rather than in four or more separate suits or enforcement proceedings.

II.

Since I conclude that there is a justiciable controversy presented and further that it would be improvident to decline jurisdiction on discretionary grounds, this would dispose of the dismissal motion were it not for the fact that defendants raise two further arguments for dismissal of the entire action and two other arguments for dismissal as to certain of the plaintiffs. All four issues so raised must be resolved against defendants, at least at this stage [fol. 97] of the proceedings:

(1) This is not an unconsented suit against the United States. Keeping in mind the distinction drawn in *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682 (1949), the thrust of the claim here is not that the Commissioner wrongly exercised his delegated powers—which would be a claim against the sovereign—but that he acted in excess of his statutory authority and therefore outside the scope of his delegated powers. And, as the Supreme Court said in *Larson*, at 689, “where the officer’s powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions.” See *Abbott Laboratories v. Celebrezze*, *supra*; *Philadelphia Company v. Stimson*, 223 U.S. 605 (1912); *Federal Trade Commission v. Nash-Finch Company*, 288 F.2d 407 (D.C. Cir. 1961).

(2) The Attorney General is not an indispensable party to this action. This was the conclusion in the *Abbott Laboratories* case where the court said at page 862: “The decree sought here does not operate against the Attorney General except in a secondary fashion. He will not be forced to do anything no matter how the court decides.”

(3) The Toilet Goods Association does have standing to sue. The members of the Association account for more than 90% of the annual sales of cosmetics in the United States. They are individually harmed and the Association, as a proper representative of the interests of its members,

can challenge the regulations in that capacity. *National Motor Freight Association v. United States*, 372 U.S. 246 [fol. 98] (1963); *Abbott Laboratories v. Celebrezze*, *supra*,

(4) Venue, predicated upon 28 U.S.C. § 1391(c), is proper as to each of the individually named plaintiffs. Although not all the Circuits agree, this Circuit has consistently held that 28 U.S.C. § 1391(c) applies to plaintiff and defendant corporations alike. *Freiday v. Cowdin*, 83 F. Supp. 516 (S.D.N.Y. 1949); *Southern Paperboard Corporation v. United States*, 127 F. Supp. 649 (S.D.N.Y. 1955); *Wear-Ever Aluminum Inc. v. Sipos*, 184 F. Supp. 364 (S.D.N.Y. 1960).

Accordingly, defendants' motion to dismiss is denied in all respects.

III.

Since the papers already submitted by the parties raise substantive issues outside this court's ordinary sphere of competence, it would be unwise to make a determination on the merits at this stage without the aid of "live", expert testimony.

To be sure, the essential questions presented in this action are ones of statutory interpretation; whatever competence the court and counsel may have in this area generally, however, can only be enhanced by a particular understanding, to be obtained with expert assistance, of the technical problems involved. Additionally, since professionally qualified representatives of both plaintiffs and defendants were present during the hearings and debates which preceded the passage of the 1960 Color Additives Amendments, it would be helpful to hear their testimony relative to legislative intent, which, presumably, they had an important role in shaping and assisting.

[fol. 99] Plaintiffs' motion for summary judgment, therefore is denied.

IV.

Inasmuch as defendants have not specified what they wish to have stricken from the complaint, their motion to strike is denied.

Settle order accordingly.

Dated: New York, N. Y.,
November 16, 1964.

H. R. Tyler, Jr., U.S.D.J.

[fol. 100]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DEFENDANTS' RENEWED MOTION TO DISMISS AND FOR
SUMMARY JUDGMENT—November 18, 1965

Sirs:

Please Take Notice that upon the complaint and answer heretofore filed herein, the annexed affidavit of Arthur S. Olick, Assistant United States Attorney, sworn to the 18th day of November, 1965, the memorandum of law served and filed herewith, and upon the Regulations for Color Additives promulgated under the Federal Food, Drug & Cosmetic Act as published in Part 8, Title 21, Code of Federal Regulations, the undersigned will move this Court in Room 2603, United States Court House, Foley Square, New York, N.Y., on the 24th day of November, 1965, at 4:00 o'clock in the afternoon of that day, or as soon thereafter as counsel may be heard, for summary judgment pursuant to F. R. Civ. Proc. 56 and Title 28, United States Code, § 2201 on the grounds that (a) the complaint fails to set forth a justiciable controversy and (b) this is an unconsented suit against the United States, or, alternatively, for an order pursuant to Title 28, United States Code, § 1292(b), certifying the said issues for an interlocutory appeal, and for such other and further relief as

[fol. 101] to the Court may seem just and proper in the premises.

Dated: New York, N.Y., November 18, 1965.

Yours, etc.

Robert M. Morgenthau, United States Attorney for the Southern District of New York, Attorney for the Defendants, By Arthur S. Olick, Assistant United States Attorney, Office & P.O. Address: United States Court House, Foley Square, New York, N. Y. 10007, Tel: 264-6319.

To: Messrs. Breed, Abbott & Morgan, Attorneys for Plaintiffs, 1 Chase Manhattan Plaza, New York, N. Y. 10005.

[fol. 102]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AFFIDAVIT IN SUPPORT OF DEFENDANTS' RENEWED MOTION
TO DISMISS AND FOR SUMMARY JUDGMENT

State of New York,
County of New York, ss.:

Arthur S. Olick, being duly sworn, deposes and says:

1. I am an Assistant United States Attorney in the office of Robert M. Morgenthau, United States Attorney for the Southern District of New York, attorney for the defendants in the above entitled action. As such, I am in charge of the defense of this action, and am fully familiar with the pleadings and proceedings heretofore had herein.

2. I submit this affidavit in support of defendants' renewed motion to dismiss the complaint for failure to state a claim or, alternatively, for leave to prosecute an interlocutory appeal.

3. The Government renews its motion to dismiss the complaint on the grounds that (a) it fails to set forth a justiciable case or controversy; and (b) that this is an uncontested suit against the United States. A previous motion by the defendants on these very same grounds, among others, was denied by this Court in an opinion filed on November 17, 1964. This was just one year ago.

[fol. 103] 4. In this action virtually the entire cosmetics industry, together with its trade association, has joined together to attack the so-called "color additive amendments" to the Federal Food, Drug & Cosmetic Act. The gravamen of the complaint is that the challenged regulations exceed the authority vested in the Food & Drug Administration by this statute. Plaintiffs ask this Court to declare the regulations null and void and to enjoin their enforcement despite the fact that plaintiffs have never sought to comply with the regulations and the Government has done nothing to enforce them against any particular company.

5. Since the Court denied the Government's initial motion, two things of significance have transpired which warrant reconsideration of the issue of justiciability. First, and most important, the United States Court of Appeals for the Third Circuit has rendered a decision in a case so substantially similar to that at bar as to be virtually determinative of this issue. In *Abbott Laboratories v. Celebrezze*, decided on November 1, 1965, the Third Circuit held that a group of pharmaceutical manufacturers and their trade association could not attack the validity of Food & Drug Administration regulations issued pursuant to the so-called drug amendments of 1962 to the Food, Drug & Cosmetic Act because of Congress' policy of limiting prior judicial review of administrative actions under this statute and because of the absence of an actual case or controversy required for justiciability under the Declaratory Judgments Act. A copy of the Court's opinion is annexed hereto [fol. 104] as Exhibit "A". In so holding, the Third Circuit reversed the Delaware District Court whose opinion was

relied upon by the plaintiffs in this case and by this Court in connection with the prior motion. Also significant, is the decision of the United States Court of Appeals for the District of Columbia in *Danville Tobacco Assn. v. Freeman*, decided on September 30, 1965. A copy of the *Danville Tobacco* decision is annexed herewith as Exhibit "B". There, the Court of Appeals chastised the District Court for considering the merits of a claim by tobacco warehousemen and their trade associations that the Secretary of Agriculture's regulations adopted under the Tobacco Inspection Act and the Commodity Credit Corporation Act were invalid. The District Court held that the regulations were valid and entered judgment for the defendant Secretary of Agriculture dismissing the complaint. The Court of Appeals modified and affirmed on the grounds that the District Court should have dismissed the complaint for failure to state a justiciable issue.

Finally, since this Court's initial decision on justiciability, the parties have conducted extensive pretrial discovery and have sought to conclude an appropriate pretrial order preparatory to a trial on the merits. This has proved exceedingly difficult since the parties cannot agree on the meaning of the subject regulations and the manner in which they are apt to be enforced. For all of these reasons, as more fully set forth in the memorandum of law accompanying this motion, deponent respectfully asks that the Court reconsider its prior determination and dismiss the complaint [fol. 105] for failure to state a claim.

6. In the event that this Court adheres to its prior determination, defendants request that the Court include in its order denying this motion the statement required by Title 28, U.S.C., Section 1292(b), to the effect that such holding involves "a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation . . .". In other words, defendants ask leave to prosecute an interlocutory

appeal. Deponent submits that there is considerable doubt with respect to whether this case can properly be tried. It may well be that plaintiffs' attack on the color additive regulations is premature. If so, a finding to that effect by the Court of Appeals will obviate the necessity for a trial and thereby foreshorten the ultimate termination of this litigation. In the circumstances of this case, to subject the parties to what will unquestionably be a long, costly and difficult trial, is to impose upon them a possibly unnecessary and clearly onerous burden. The issue of justiciability is such that it must ultimately be determined by the Court of Appeals. Certainly, justice requires an appellate review of this issue before the parties are subjected to a plenary trial. It is already apparent from the proposed pretrial order in this case that numerous documents will be introduced at a plenary trial and that some 19 witnesses may be called. Moreover, the parties have encountered considerable difficulty in agreeing on the precise issues presented for adjudication on the merits.

[fol. 106] 'Wherefore, deponent respectfully prays that defendants' motion for summary judgment be granted and that the complaint herein be dismissed.

Arthur S. Olick, Assistant United States Attorney.

(Sworn to November 18, 1965.)

[fol. 122]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AFFIDAVIT OF EDWARD J. ROSS—Dated November 23, 1965
State of New York,
County of New York, ss.:

Edward J. Ross, being duly sworn, deposes and says:

1. I am a member of Breed, Abbott & Morgan, attorneys for all plaintiffs herein, and am in charge of this action.

2. Plaintiffs' opposing memorandum shows that *Abbott Laboratories v. Celebrezze* and *Danville Tobacco Assn. v. Freeman* do not provide any basis for this Court's changing its decision that the Color Additives Regulations (the "Regulations") are subject to judicial review.

3. The purpose of this affidavit is to set before the Court in proper form certain documents and testimony before trial by officials of the Food and Drug Administration ("FDA"), which establish the immediate and substantial impact of the Regulations on the entire cosmetic industry, and show that they are legislative, and to correct certain misstatements in the affidavit of Arthur S. Olick, sworn to November 18, 1965 (the "Olick affidavit").

A. *Premarketing Clearance of All Finished Cosmetic Products Which Color the Body*

[fol. 123] 4. The Olick affidavit, in seeking to show that there may be no controversy because "Plaintiffs' attack on the color additive regulations is premature" (Para. 6), states that "the parties cannot agree on the meaning of the subject regulations and the manner in which they are apt to be enforced" (Para. 5).

5. *The parties are not in disagreement as to the meaning of the Regulations.* This action does not involve any issue as to their proper interpretation. Plaintiffs have accepted, for purposes of this case, both the plain language of the Regulations and the statements by FDA officials in press releases and in depositions as to the scope and effect of the Regulations.

6. There is no dispute that the Regulations require pretesting, listing and certification of *substantially all finished cosmetic products*, including those generally recognized as safe; that the Regulations require pretesting, listing and certification of all, or substantially all, the ingredients of such cosmetics; that the Regulations require

pretesting, listing and certification of hair dye products previously exempt; and that the Regulations give FDA inspectors access to the formulae of finished cosmetic products. This is all made abundantly clear from the Regulations, FDA releases, defendants' answers to interrogatories, and the testimony of Mr. Harvey and other FDA officials.

7. The Regulations state (§ 8.1(f)):

"Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are [fol. 124] 'color additives'."

8. By defining a "color additive" to include finished products, and by requiring the pretesting, listing and certification of such products, the Regulations impose a comprehensive system of premarketing clearance *on all finished cosmetic products which color the body*. This was stated in the FDA release, dated June 22, 1963 (Exh. A hereto), announcing the Regulations:

"Under the new regulations, FDA will require that an entire product—not just the color ingredient—be shown by the manufacturer to be safe before it is released for sale."

That release also described the provision for the premarketing clearance of the "entire product" as being a "new requirement," and noted that prior to the Regulations "only color . . . ingredients had been subject to the requirement for pre-marketing proof of safety."

9. Mr. Harvey testified that such release very clearly advised industry that the entire cosmetic must now be cleared in advance by FDA (Tr. pp. 309-10):

"Q. Now, isn't that a fact that this is a very plain and very clear statement that from the issuance of the regulations, the entire cosmetic products must be shown safe before it may be released for sale? A.

The cosmetic product for applying color to the human body—

[fol. 125] "Q. Yes. A. Yes.

"Q. It was very plainly stated in this press release, was it not? A. Yes, I think it is plain.

"Q. And industry had no doubt as to what was meant by it; is that correct? A. I can more accurately report my own view that I can that of industry. It does seem clear.

"Q. And is this what is meant by the term 'pre-marketing clearance of cosmetics'? A. Yes, I think that is true, to the extent that this refers to certification or clearance of certain cosmetics, it would be a pre-marketing clearance of cosmetics, which also happened to be color additives."

10. That this is still FDA's official position is evident from defendants' answers to interrogatories, dated October 29, 1965, sworn to by William W. Goodrich, Assistant General Counsel for FDA. Interrogatory 10 asked defendants to—

"Specify the finished cosmetic products which FDA contends are required to be pretested, listed and certified, under the provisions of the Color Amendments and the Color Regulations."

Defendants' answer states:

"Any cosmetic intended to impart color to the human body would have to be listed as safe for its intended use before it could be used."

Mr. Harvey's testimony confirms this (Tr. p. 310):

"Q. And under your view, or the view of the FDA, [fol. 126] any cosmetic which imparts a color to the body is a color additive? A. That's right, *would require listing.*"

11. Mr. Harvey also made it clear that in order to obtain listing, the Regulations require "full reports of adequate tests," including "detailed data derived from appropriate animal and other biological experiments" (Tr. p. 413). He agreed such testing and detailed information would "be required in connection with applications for listing rouge, leg applications, pancake makeup," and all other finished cosmetic products which color the body (Tr. pp. 413-14).

12. The enormous burden and cost imposed by the Regulations on the cosmetic industry, particularly with respect to the testing and listing of every finished cosmetic product which colors the body, was illustrated in the affidavit of Charles R. Kircher, sworn to March 25, 1965, in support of plaintiffs' summary judgment motion. As there noted, the cost of complying with the Regulations "would be so prohibitive, it would substantially destroy Kolmar's entire domestic cosmetic business." A similar fate would be decreed for many other plaintiffs.

*B. Premarketing Clearance of Cosmetics Which
Do Not Color the Body and Substantially All
Their Non-Color Ingredients*

13. The Regulations also require premarketing clearance, including pretesting, listing and certification, of all [fol. 127] finished cosmetic products which contain a color, even if they do not impart color to the body. This would catch substantially all cosmetics.

The Regulations define "color additives" to include "all diluents" (§ 8.1(f)). They then define "diluent" as "any component of a color additive mixture * * * intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body" (§ 8.1(m)). *Since (essentially every ingredient facilitates the use of the color, substantially all the non-color ingredients of all finished cosmetic products which contain a color would also be subject to premarketing clearance.*

14. This was made clear by David J. Miller, principal draftsman of the Regulations (Tr. p. 39):

"Q. Let me understand this, Mr. Miller. Under the Color Regulations is 'diluent' in effect defined to include every ingredient of every cosmetic product that contains a color? A. I would say essentially yes."

15. Thus, not only do the Regulations require pre-marketing clearance of all finished cosmetic products which impart color, but also those cosmetics which contain a color and essentially all the non-color ingredients of such cosmetics. In fact, when Mr. Miller was asked to state those cosmetics which would not be covered by the Regulations, he could only specify "a cold cream containing no color whatsoever" (Tr. p. 41). However, since the Act defines "white" as a "color" (§ 201 (t)(2)), even cold cream [fol. 128] could be covered by the Regulations.

C. Repeal of the Statutory Exemption For Hair Dye Products

16. Section 601(a) and (e) of the Act contain an across-the-board exemption for hair dye products, subject to the statutory label required by Section 601(a). The Regulations change such exemption in two ways:

First, by defining a color additive to include "Lipstick, rouge, eye makeup colors and *related cosmetics intended for coloring the human body*" (§ 8.1(f)), the Regulations place hair dye products in the same category as all other cosmetics which color the body, and require the same pre-marketing clearance for such hair dye products.

Second, the Regulations expressly limit the exemption in Section 601(a) of the Act to hair dye products whose sole potential adverse effect is skin sensitization. According to the Regulations (§ 8.1(u)), "the exemption does not apply" to all the hair dye products.

17. Accordingly, the FDA release (Exh. A) accompanying the Regulations states:

"The patch testing requirement offers no protection from other types of toxicity, Commissioner Larriek said, and the purpose of the new regulation is to close this gap. Hair dyes that do not cause a reaction with the patch test must now be demonstrated to be safe before they can be marketed."

[fol. 129] 18. A subsequent FDA release, dated October 3, 1963 (Exh. B), candidly describes the Regulations as "limiting the exemption for hair dyes under the Federal Food, Drug, and Cosmetic Act." What better example of a "legislative" regulation than one which admittedly changes a statutory exemption?

19. The October 3, 1963 release (Exh. B) also shows the immediate effect of the Regulations. With respect "to new hair dye formulations coming on the market," the release states the regulation "applies immediately." "Products currently being marketed will not be affected until June 22, 1965."

20. The fundamental change in the statutory provisions relating to hair dye products is underscored by Mr. Harvey's testimony as to the practice prior to the Regulations (Tr. pp. 88-9):

"Q. Then is it your testimony that assuming a hair dye product contained the statutory label, hair dye products were totally exempt from the Act; is that correct? A. Well, they were not required to be certified if they met those specifications, yes.

"Q. They were not required to be listed? A. That's right.

"Q. And assuming that the hair dye product and its coal-tar ingredient were neither listed nor certified, was it not a fact that the hair dye was also exempt from the provisions of Section 601(a) of the Act, if

it bore the statutory label? A. Well, I believe it was so held at one time, counselor, yes.

[fol. 130] "Q. And at which time was that, which period would that be? A. So far as I am concerned, I had that view, oh, up to perhaps a year ago, something like that."

21. Not only do the Regulations now require listing and certification of finished hair dye products, but they also require the pretesting, listing and certification of all the non-color ingredients of such products.

Accordingly, though Congress has granted an exemption for all hair dye products which bear the statutory label, in effect since 1938, the Regulations seek to repeal such exemptions and to plug what FDA calls a "gap" in the law. The substantial and practical impact on plaintiffs, as well as the "legislative" nature of the Regulations, are self-evident.

22. It could hardly be clearer from the testimony of Mr. Harvey and other FDA officials, from the FDA releases, and from the language of the Regulations themselves, that industry is now required by the Regulations to obtain FDA clearance for substantially every cosmetic marketed today, including all hair dye products, as well as the separate ingredients of such cosmetics. There is no difference of interpretation as to this requirement, and FDA cannot avoid determination of whether such requirement exceeds its statutory authority by now suggesting the Regulations are not clear, and "the parties cannot agree on the meaning of the subject regulations" (Olick Aff., Para. 5).

[fol. 131] 23. The Olick affidavit also states that because of the alleged uncertainty of the Regulations it has been "exceedingly difficult" for the parties to "conclude an appropriate pretrial order" (Para. 5). This is not my understanding. I submitted to Mr. Olick a proposed pretrial order on September 2, 1965, and I received his comments on September 27 and October 7, 1965. On October 20, 1965,

we conferred with the Court in Chambers to resolve the differences, and agreed on a format. On October 25, 1965, I sent Mr. Olick a copy of the revised pretrial order, which reflected the format as agreed upon between counsel and the Court. I never received any objections. On the contrary, I understood from Mr. Olick that the pretrial order was satisfactory. The reason it has not been presented to this Court for signature is because of the postponement of the trial until disposition of this renewed motion to dismiss.

D. Bills For The Premarketing Clearance Of Cosmetics

24. Plaintiffs' original memorandum (pp. 61-65), dated April 10, 1964, noted that whenever the Act requires premarketing clearance of a finished product or of ingredients on a broad basis, there is an exception for those products or ingredients which are generally recognized as safe for use. This same practice was followed in the many bills introduced over the years for the premarketing clearance of cosmetics. (Copies of three such bills are annexed hereto as Exhibit C.) Even H.R. 6788 and H.R. 11582,—bills which Mr. Ellenbogen testified were prepared and sponsored by HEW (Tr. pp. 276-7),—expressly exclude cosmetics which are generally recognized as safe for use.

25. Thus, the Regulations are even more sweeping in scope and coverage than any of the cosmetic bills which Congress has rejected. The Regulations do not exclude cosmetics which are generally recognized as safe for use, but require all cosmetics, even if safely used for 50 years or more, to be subject to the same premarket procedures as a new cosmetic formulation.

26. Significantly, both H.R. 6788 and H.R. 11582 were introduced after enactment of the Color Additive Amendments of 1960. Mr. Ellenbogen testified that cosmetic legislation was needed in order "to complete the protection of the consumer with respect to pre-marketing of cosmetics

• • • [since] the Color Additives Provision did not cover them all" (Tr. pp. 300-301). However, when asked to name any cosmetic which FDA did not consider already "covered by the Color Additive Amendments of 1960," he did not "know of any" and could not "name any offhand" (Tr. pp. 301-302). He was "not sure" whether all toothpastes were covered (Tr. p. 302).

27. Finally, Mr. Ellenbogen's testimony shows the anomaly of the Regulations since, under FDA's view, even if a cosmetic is generally recognized as safe for use and therefore excluded from the premarketing clearance provisions of H.R. 6788,—the cosmetic bill last before Congress,—"It would still be covered by the • • • Color Additive Amendments of 1960" (Tr. pp. 302-303).

[fol. 133]

E. Compliance With the Regulations

28. The Olick affidavit states "that plaintiffs have never sought to comply with the regulations" (Para. 4). This is simply not true. *It is only with respect to the testing, listing and certification of finished cosmetic products that plaintiffs have failed to comply with the Regulations.*

29. Promptly after enactment of the Color Additive Amendments, industry representatives had frequent meetings with FDA scientists during which they discussed and agreed upon the methods and procedures for testing the color ingredients added to cosmetic products. As noted in the affidavit of Fuller Holloway, sworn to March 24, 1964, as a result of the testing procedures agreed to with FDA, industry has "arranged with independent clinical laboratories to perform the necessary testing for approximately 25 colors to be listed for use in cosmetics" (p. 7).

Industry has submitted periodic reports to FDA on the progress of such tests, and FDA has been kept fully advised of all technical data, as developed.

30. The testing required by the Regulations, with respect to just the color ingredients, is extremely time consuming. *Accordingly, FDA has extended the closing date for listing of the color ingredients added to food, drugs and cosmetics.* However, no comparable extension has been granted with respect to the listing of lipstick, rouge, eye makeup or any other finished cosmetic product. Only after [fol. 134] this action commenced did FDA advise industry that the Regulations would not be enforced against such products, but only during the pendency of this action. FDA has never stated that such nonenforcement would continue after this action terminated were defendants to prevail. Indeed, were the Court to decide in defendants' favor, whether on jurisdictional grounds or on the merits, all finished cosmetic products which color the body or which contain a color would be subject to immediate seizure, and their manufacturers to criminal penalties.

- F. *Miscellaneous*

31. Although defendants have renewed the motion previously made, their present motion is not made upon the affidavits and other documents submitted on the prior motion. This may be an oversight. In any event, it would appear proper to have before the Court the affidavits on the prior motion, so that there can be no question as to plaintiffs' right to rely upon them in the event of an appeal. Accordingly, these are incorporated herein by reference.

Wherefore, deponent respectfully prays that defendants' motion to dismiss the complaint be denied.

Edward J. Ross.

(Sworn to November 23, 1965.)

[fol. 135]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REPLY AFFIDAVIT OF ARTHUR S. OLICK—
Dated December 1, 1965

State of New York,
County of New York, ss.:

Arthur S. Olick, being duly sworn, deposes and says:

1. I submit this affidavit in reply to the affidavit of Edward J. Ross, sworn to November 23, 1965, submitted by plaintiffs in opposition to defendants' renewed motion to dismiss the complaint and for summary judgment in their favor.

2. Mr. Ross' affidavit clearly manifests the illusory nature of the instant litigation. What the plaintiffs have done, through their counsel, is to take issue with the interpretations given the Color Regulations by various officials of the Food and Drug Administration (hereinafter called FDA). Whereas, the complaint and the answer purport to raise the question of whether or not the Color Additive regulations conform with the statute upon which they are based and which they seek to implement, this lawsuit has degenerated into an argument between the cosmetic industry and the Food and Drug Administration as to how the Regulations are to be interpreted and applied. Deponent submits that this Court is not the appropriate forum for resolving such a controversy. The statute itself, as well as the Regulations, afford ample opportunity for testing the validity of FDA's position within the context of specific cases.

[fol. 136] 3. In his affidavit Mr. Ross blatantly states that the "Parties are not in disagreement as to the meaning of the Regulations" (para. 5). With equal facility he then

goes on to state that the Regulations require "FDA clearance for substantially every cosmetic marketed today, including all hair dye products, as well as all the separate ingredients of such cosmetics" (para. 22). The Regulations, on their face, require no such thing. The final Regulations relating to color additives [28 F.R. 6439, June 22, 1963] require the pre-testing only of that limited class of cosmetics which may properly be defined as color additives within the meaning of the statute. The Regulations set forth the conditions that must be met in the marketing of cosmetics of this class. Regulations section 8.1(f) defines "Color Additives" in the very same language utilized in the statute and then goes on to give examples of *certain* finished cosmetic products which are deemed to be included in such definition. The point which must be emphasized is that the statute itself defines "Color Additives" to include specifically those substances, whether finished cosmetic products or not, that impart color to the human body. The FDA has made it clear that a cosmetic such as lipstick, rouge or eye shadow which directly or through reaction colors the human body is to be regarded as a color additive. However, it does not necessarily follow, as assumed by the plaintiffs, that every color additive which colors the human body must be individually listed. FDA has repeatedly stated its intention to prepare a list of diluents which may safely be used in these color additives. If a manufacturer then uses a straight color [fol. 137] which has been listed and suitable diluent on this diluent list, in a lipstick for example, the individual listing of the lipstick is not required. David J. Miller of FDA, described by Mr. Ross (para. 14) as the "principal draftsman of the Regulations", has so stated on numerous occasions. Unless and until the plaintiffs seek the listing or exemption of their color additives, or those finished cosmetic products which might be regarded as color additives, it is pure unadulterated speculation on their part to insist that FDA will "require pretesting, listing and certification of substantially all finished cosmetic prod-

ucts, including those generally recognized as safe . . . " (para. 6).

4. Both the statute itself and the Regulations provide ample opportunity for the plaintiffs to test FDA's intentions. There are extensive provisions for listing, certification and exemption on petition of any manufacturer. FDA is required by law to publish these petitions, to hold hearings, to secure the views of qualified experts and to subject its determinations to judicial review. This is clearly the route contemplated by the Congress and it is the route the plaintiffs should be compelled to travel.

5. Plaintiffs repeat their argument that the Regulations impose an enormous burden and cost upon them. Certainly the Congress contemplated a significant financial burden on the cosmetic industry when it specifically provided for testing of color additives, listing and certification of color additives, and fees for such listing and certification. That certain cosmetic manufacturers might find these costs [fol. 138] prohibitive is irrelevant in the context of the manifest Congressional intent to protect the public health and welfare. Moreover, any such claim is purely speculative since the plaintiffs have never sought to comply with the statute or the Regulations and do not really know just how much testing the FDA will require in any given case.

Wherefore, deponent respectfully prays that the motion be granted and the complaint dismissed.

Arthur S. Olick, Assistant United States Attorney.

(Sworn to December 1, 1965.)

[fol. 139]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SUPPLEMENTAL AFFIDAVIT OF EDWARD J. ROSS
—Dated December 3, 1965

State of New York,
County of New York, ss.:

Edward J. Ross, being duly sworn, deposes and says:

1. I am a member of Breed, Abbott & Morgan, attorneys for all plaintiffs herein.

2. Defendants' reply memorandum, served December 1, 1965, states that "These plaintiffs * * * have made no attempt to either comply with the regulations or to secure exemption therefrom. *Not a single petition for listing, certification or exemption has been filed*" (p. 8).

The Olick affidavit, sworn to November 18, 1965, states "that plaintiffs have never sought to comply with the regulations" (para. 4). Defendants' prior memorandum states "Plaintiffs have not bothered to seek certification or listing of any of their products or components * * *. All plaintiffs need do to test the FDA's definition of a color additive, for example, is to request listing and certification of a particular dye separate and apart from the finished cosmetic product in which it is used" (p. 6).

3. The foregoing statements are not true insofar as they relate to dyes or pigments, which plaintiffs claim are the color additives intended by Congress to be listed. [fol. 140] Beginning May 12, 1965 petitions were submitted to FDA for the listing of various color additives, as follows:

Ext D&C Yellow No. 7	(CAP [Color Additive Petition] No. 26)	May 12, 1965
D&C Reds No. 8 & 9	(CAP No. 28)	May 18, 1965
D&C Reds No. 10, 11, 12 & 13	(CAP No. 29)	May 18, 1965
D&C Red No. 31	(CAP No. 32)	June 30, 1965
D&C Yellows No. 7 & 8	(CAP No. 34)	July 26, 1965
D&C Orange No. 4	(CAP No. 35)	August 2, 1965
D&C Violet No. 2		September 30, 1965
D&C Red No. 34		October 22, 1965
D&C Red No. 17		November 4, 1965
D&C Reds No. 6 & 7		November 15, 1965

[fol. 141] 4. A typical letter of transmittal is as follows:

July 26, 1965

Commissioner of Food and Drugs
Food and Drug Administration
Department of Health, Education and Welfare
Washington 25, D.C.

Dear Sir:

Petitioner submits this petition pursuant to Section 706 (b)(1) of the Federal Food, Drug, and Cosmetic Act, requesting listing by the Commissioner of the color additive D&C Yellow No. 7 and related D&C Yellow No. 8 as suitable and safe for use in drugs and cosmetics that are applied externally.

Attached hereto in triplicate and constituting a part of this petition are the following:

- A) The name and all pertinent information concerning D&C Yellow No. 7 and D&C Yellow No. 8 and the substances used in the manufacturing process.
- B) The amount of D&C Yellow No. 7 and D&C Yellow No. 8 to be used and directions regarding the proposed use of color additives.

- C) Practicable methods to determine D&C Yellow No. 7 and D&C Yellow No. 8 and other components of the color additives.

[fol. 142]

- D) Full reports of investigations made with respect to the safety of D&C Yellow No. 7.
- E) Date indicating the probable consumption and/or other relevant exposure to D&C Yellow No. 7 and D&C Yellow No. 8.
- F) Proposed regulation governing the use of D&C Yellow No. 7 and related D&C Yellow No. 8 in externally applied drugs and cosmetics.
- G) Exemption from batch certification—not requested.
- H) Alteration of existing regulation—not applicable.

Listed numbers appearing in the test of the petition refer to references which will be found at the end of the petition.

A certified check payable to the order of the Food and Drug Administration in the amount of \$2600 is enclosed herewith as the prescribed deposit.

Sincerely yours,

Hazleton Laboratories, Inc.

Robert A. Scala, Ph.D.

Consultant to:

The Toilet Goods Association, Inc.

[fol. 143] 5. It will be noted that the attachments to the petition set forth the information required by the Regulations, including "Full reports of investigations made with respect to the safety of D&C Yellow No. 7."

It will also be noted that each petition was accompanied by a certified check to the order of FDA, in the amount of \$2,600, as the deposit required under the Regulations.

6. Petitions have been submitted with respect to 16 separate dyes. To date, no response has been received from FDA as to any of the petitions, and the petitioner is simply awaiting action by FDA.

7. None of the plaintiffs have applied for certification, as defendants state, since certification has to follow the granting of a listing application. Until the color additive is listed, an application for certification cannot be made.

Edward J. Ross

(Sworn to December 3, 1965.)

[fol. 144]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AFFIDAVIT OF A. S. OLICK—Dated December 6, 1965

State of New York,

County of New York, ss.:

Arthur S. Olick, being duly sworn, deposes and says:

1. Plaintiffs in an affidavit to be filed with the Court on December 6, 1965, assert that they have sought to comply with the Color Additive Amendments to the Federal Food, Drug and Cosmetic Act by filing petitions for listing. Some 10 petitions have indeed been filed with the Food and Drug Administration seeking the listing of certain specific colors for external use. These were filed between May and November of 1965.
2. All 10 of these petitions are patently deficient because they do not specify the conditions of intended use for the subject colors as required by the Act. Four of the listing petitions are also deficient because they involve experimental work by a laboratory that has been disqualified by FDA. All of these facts have been orally communicated to the respective petitioners and this information comes as no surprise to them.
3. Because of the pendency of this lawsuit, these petitions have not yet been acted upon although the petitioners have been told that they are inadequate.

Arthur S. Olick, Assistant United States Attorney.

(Sworn to December 6, 1965.)

[fol. 145]

IN THE UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Docket No. 30261

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.;
 AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE
 BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.;
 CHESEBROUGH-POND'S INC.; CHRISTIAN DIOR, PERFUMES
 CORP.; CLAIROL INCORPORATED; COLONIAL DAMES CO.,
 LTD.; COTY, INC.; FABERGÉ INC.; FRANCES DENNY, INC.;
 THE FULLER BRUSH CO.; THE GEORGE W. LUFT CO.,
 INC.; THE GILLETTE COMPANY; A. M. HANSEN, doing
 business as HOUSE OF HOLLYWOOD; HARPER METHOD,
 INC.; HELENA RUBINSTEIN, INC.; HELENE CURTIS INDUS-
 TRIES, INC.; HENRY/HARAN/HUTCHINGS, INC.; HERBOLD
 LABORATORY, INC.; JOHN H. BRECK, INC.; KOLMAR LABO-
 RATORIES, INC.; LADY LENNOX COMPANY, INC.; LEHN &
 FINK PRODUCTS CORPORATION; ARNOLD L. LEWIS, doing
 business as STUDIO COSMETIC CO.; MAX FACTOR & CO.;
 MAYBELLINE CO.; MERLE NORMAN COSMETICS, INC.; JACK
 B. NETHERCUTT, doing business as NETHERCUTT LABORA-
 TORIES; NEUTROGENA CORP.; NUTRILITE PRODUCTS, INC.;
 OLD 97 COMPANY; PRIVATE LABEL COSMETICS CO., INC.;
 PURITAN COSMETICS CO.; REVLON, INC.; ROUX LABORA-
 TORIES, INC.; SHULTON, INC.; and YARDLEY OF LONDON,
 INC.; Plaintiffs-Appellees,

against

ANTHONY J. CELEBREZZE, Secretary of Health, Education
 and Welfare, and GEORGE P. LARRICK, Commissioner of
 Food and Drugs, Defendants-Appellants.

Appendix to Appellees' Brief—Filed February 18, 1966

[File endorsement omitted]

[fol. 147]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
Civil Action No. 63 Civ. 3349

THE TOILET GOODS ASSOCIATION, INC. *et al.*, Plaintiffs,
against

ANTHONY J. CELEBREZZE, Secretary of Health, Education
and Welfare; *et ano.*, Defendants.

AFFIDAVIT—March 25, 1964

State of Wisconsin,
Milwaukee County, ss:

Charles R. Kircher, being first duly sworn, on oath deposes and says:

I am a chemical engineer and a vice-president and director of Kolmar Laboratories, Inc. ("Kolmar"), one of the plaintiffs in the above action. I have been associated with Kolmar for 29 years. I have studied the Color Regulations promulgated by the Food and Drug Administration (FDA), 28 F. R. 6439, and the cost to Kolmar of complying with them. This cost would be so prohibitive, it would substantially destroy Kolmar's entire domestic cosmetic business.

Kolmar has been engaged in the manufacture and sale of cosmetics for 43 years. Its finished cosmetic products are manufactured for and sold to other cosmetic companies for resale under their own labels and brand names. It is the largest such private label cosmetic manufacturer in the world. It services 397 customers in the United States, many of whom are small cosmetic companies who rely exclusively on Kolmar and other private label manufacturers [fol. 148] for supply. Kolmar makes a complete line of cosmetics, including lipstick, rouge, eye makeup, nail polish and face powder. These and other cosmetics that color the

body account for approximately 60% of its total dollar sales.

Kolmar manufactures and sells in excess of 2,700 different formulae or finished cosmetic products that color the body. All of such products come within the Color Regulations definition of a "color additive." As a result, each of these finished products must be listed, and a fee of \$2,600 must accompany each listing petition. Thus, it would cost Kolmar some \$7 million in fees just to list its finished cosmetic products that color the body.

While these fees are alone sufficient to drive Kolmar out of business, the Color Regulations do not stop there. They also require a separate listing for each "diluent" in a finished cosmetic product. A diluent has always been defined by chemists and others in the FDA and the cosmetic and color industries as the substance used to dilute the strength of the dye, pigment or other pure coloring substance. But the Color Regulations redefine diluent to mean substantially all the ingredients of a finished cosmetic product other than the color ingredient. Kolmar uses 264 of such non-coloring ingredients in its finished cosmetic products. By virtue of the expanded definition of a diluent, Kolmar could not use these ingredients until they have been listed. The listing fee for each such ingredient is \$250.

While FDA has, on its own initiative, listed 65 of these ingredients for use in specified types of cosmetic products, Kolmar would still have to apply for listing of the remaining 199 and any of the 65 ingredients that are to be used in cosmetics not covered by the FDA listing.

It is possible that other cosmetic manufacturers will apply for and obtain listing of some of these same 199 ingredients, and this may reduce Kolmar's listing fees. [fol. 149] Another major expense is imposed by the requirement that each listing petition be supported by extensive physical and chemical tests. These tests must establish, among other things, the physical, chemical and biological properties of the ingredients sought to be listed, and other detailed data derived from animal and biological

experiments. Separate tests would be required for each of Kolmar's 2,700 finished cosmetic products. We have been notified by an independent clinical testing laboratory that the cost of performing the minimum tests for one product would be \$3,000. This cost is broken down as follows:

1. Primary irritation tests with rabbits—\$50.00.
2. Acute dermal toxicity tests with rabbits—\$125.00.
3. Sub-acute dermal toxicity tests 90 days, 12 rabbits—\$1000.00.
4. Human patch tests, 25 people under qualified dermatologist—\$1800.00.

On this basis it would cost Kolmar \$8,100,000.00 for minimum testing. However, FDA has advised us that such minimum tests would not be sufficient. They have indicated, for instance, that patch tests on 25 people are not significant and suggest a minimum of 200 people. This would increase the patch test costs by eight times or \$14,400.00 for each finished cosmetic product. This, in turn, would increase the total testing expense from \$8,100,000.00 to \$42,120,000.00.

Since the Color Regulations also require listing of the non-color ingredients of a finished cosmetic product, these ingredients would also have to be pretested. The cost for the minimum testing for these ingredients would be \$597,000.00. As a result of the increased testing suggested by the FDA, the cost would be \$3,104,000.00.

Another major item of costs is imposed by the certification requirements of the Color Regulations. The Color Regulations impose a minimum certification fee of \$100.00 [fol. 150] for each batch of color additives certified. Kolmar manufactures on the average of 150 batches of cosmetics that color the body per week. Over the period of one year certification fees for this number of batches would be \$750,000.00.

The certification provision and other provisions of the Color Regulations also require detailed record keeping and

other administrative burdens that would force Kolmar to employ approximately five additional full time employees just to comply with these aspects of the Regulations.

In addition to the above described financial burdens, the Color Regulations would materially discourage Kolmar's research and scientific development work in the cosmetic field. Since the Color Regulations require a finished cosmetic product and all its ingredients to be listed, which listing would be published in the Federal Register, Kolmar would be forced to disclose the identity of many cosmetic ingredients that it has developed over a period of years at great cost. These secret ingredients would thus be made available to others who did not share in the development costs.

Charles R. Kircher

Sworn to March 25, 1964.

[fol. 151]

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AFFIDAVIT—April 3, 1964

State of New York,
County of New York, ss.:

Dr. Samuel Zuckerman, being duly sworn, deposes and says:

1. I am a Vice President of H. Kohnstamm & Co., Inc. ("Kohnstamm"), a color manufacturer. I am a graduate chemist and have been closely connected with the production and testing of colors for 28 years. I am familiar with the Federal Food, Drug and Cosmetic Act ("Act"), the Color Additive Amendments of 1960, the Color Regulations purported to be promulgated thereunder by the Food and Drug Administration ("FDA"), and I am generally familiar with all FDA regulations concerning colors for use in or on food, drugs or cosmetics.

2. The color industry, which has annual sales of less than \$10,000,000, includes, in addition to Kohnstamm, the following companies: Allied Chemical Corp.; Bates Chemical Co., Inc.; Wm. J. Strange & Co.; Sterwin Chemicals, Inc.; Warner-Jenkinson Manufacturing Co.; and Ansbacher-Siegel Corporation.

The color ingredients manufactured by these companies are purchased by food, drug or cosmetic manufacturers and are added to said articles for the purpose of imparting color thereto, or, in the case of cosmetics, to enable the article to color the body. Such color ingredient is either a dye, pigment or some other coloring substance. Dyes, which are soluble, and pigments, which are insoluble, not only impart color but are themselves colors. There are other substances which impart color but which differ from dyes and pigments in that they are themselves colorless. An example of such other substance is dihydroxy acetone, [fol. 152] used in the cosmetic product "Man-Tan". This is a clear substance that imparts a color when applied to the body.

3. There are two general categories of colors:

(i) Natural colors, which are derived from animal, vegetable or mineral; and

(ii) Synthetic colors, which are made by a process of synthesis.

The discovery of dye synthesis by Perkins in 1856 led to the production of synthetic organic colors. Synthetic organic colors were found to be generally superior to natural colors in uniformity, tinctorial value and application properties, and therefore became the most widely used color additives in food, drugs and cosmetics. The synthetic dyes and pigments most widely used as such color additives are chemical compounds which are or can be derived from coal-tar or coal-tar constituents, known as "coal-tar colors".

The first Food and Drug Act (1906) did not cover cosmetics, and did not require the listing or certification of

the color additives added to food, drug or cosmetic products. However, the Secretary of Agriculture, who administered the 1906 Act, promulgated for industry guidance a list of "coal-tar colors", with specifications, which were harmless and safe for use. The color manufacturers voluntarily submitted samples from each batch of "coal-tar colors" to the Department of Agriculture to assure compliance with the specifications.

Under the 1938 Act, color additives added to food, drug or cosmetic products were required to be listed and certified. But this requirement was limited only to the "coal-tar colors"—the natural colors were not covered by the listing and certification requirements of the 1938 Act.

Included among such natural colors are certain dyes which are not only used to color foods, drugs or cosmetics, but which themselves are food, drug or cosmetic articles. Beet juice and cottonseed flour are examples of food articles [fol. 153] that are used to color other articles. Beta carotene and riboflavine are examples of vitamins or drugs which are also used to color other products. Talc is an example of a cosmetic which is also used to color other articles.

4. A dye or pigment, in its purified state, is stronger than required for its function of imparting color to food, drug or cosmetic products. Accordingly, the dye or pigment is diluted or increased in volume by an inert substance called a "diluent". Before such dilution, the dye or pigment is called a "straight color". FDA's regulations under the 1938 Act recognized that the diluent is added to the color; it is not itself a color, and did not have to be listed. This long-standing interpretation and practice has now been abolished by the Color Regulations. The Regulations define "color additive" to include "all diluents", and define "diluent" as any compound of a color additive mixture which facilitates use of the mixture. Since every ingredient of a cosmetic product containing a color mixture facilitates use of the mixture, all such non-coloring ingredients be-

come "diluent", subject to pretesting, listing and certification.

Finished cosmetic products contain hundreds of other ingredients in addition to the straight color additive and the diluent. For example, a typical lipstick may contain, in addition to the color and diluent, the following other ingredients: Wax, Candelilla Wax, Beeswax, Carnauba Wax, Ozokerite, Ceresin, Caster Oil, Lanolin, Butyl Stearate, Lecithin, Petrolatum, Cetyl Alcohol, Fragrance, Propyl Paraben, Isopropyl Myristate and Diethyl Sebacate. These ingredients perform one or more functions for a finished lipstick product, such as to prevent running, to create an emollient effect, to reduce viscosity, and to provide a pleasant fragrance. These and hundreds of other non-coloring ingredients have been used in lipsticks and other cosmetics for many years. FDA has never before defined them as color additives or diluents, and has never required that they be listed or certified.

Samuel Zuckerman.

Sworn to April 3, 1964.

[fol. 154]

IN UNITED STATES DISTRICT COURT
U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration
Washington 25, D. C.

FOR RELEASE IN A.M. PAPERS

Saturday, June 22, 1963

The Food and Drug Administration today announced regulations for assuring the safety of color additives used in foods, drugs, and cosmetics. The regulations were published in today's Federal Register.

FDA said the regulations implement the Color Additive Amendments to the Federal Food, Drug, and Cosmetic

Act, and have taken into account comments and suggestions made in response to proposed regulations published earlier.

Commissioner of Food and Drugs George P. Larrick pointed out the following specific changes in existing procedures and interpretations which he said would strengthen consumer protection from possibly unsafe colors:

1. Additional safety precautions are provided for lipsticks, rouge, eyebrow and lash color and other substances that apply color to the human body. Under the new regulations, FDA will require that an entire product—not just the color ingredient—be shown by the manufacturer to be safe before it is released for sale.

Previously only color of the coal tar type ingredients had been subject to the requirement for pre-marketing proof of safety.

Commissioner Larrick said the new requirement is based on the language in the law and the legislative intent to insure that the entire formulation of a "color additive" is safe for the consumer.

2. The language of the regulation dealing with exemption of hair dyes from the safety clearance and certification requirement has been clarified to show that the "patch [fol. 155] test" requirement applies only to hair dyes which are dangerous because the user may be sensitive to them.

Thursday, October 3, 1963

Commissioner Larrick said that the exemption in the 1938 law was conditioned on a labeling requirement calling for the use of a patch test to determine whether the user is sensitive to the color before the hair dye is applied. The patch testing requirement offers no protection from other types of toxicity, Commissioner Larrick said, and the purpose of the new regulation is to close this gap. Hair dyes that do not cause a reaction with the patch test must now be demonstrated to be safe before they can be marketed.

3. The regulations provide that FDA may refuse to certify a color additive—and thus in effect ban it from the

market—if the manufacturer refuses FDA inspectors access to manufacturing facilities, processes, and formulas involved in manufacture of the additive.

This provision does not represent a change in policy, Commissioner Larrick said, but the new regulations spell out the policy more specifically. He said that the FDA cannot determine whether the conditions for safe use of color additives, including products exempt from certification, are being met unless a complete inspection of the plant and formulas can be made.

The new regulations also outline for manufacturers the type of experimental data and other information which will be required and how to submit it to obtain safety clearance for permanent listing and setting of safe tolerances for color additives. The regulations cover such matters as definition of terms, fees to be charged for listing and certification of batches of colors, labeling requirements for colors, time schedules for acting upon petitions, protection of trade secrets, procedures for obtaining certification, or exemption from certification of batches of both coal tar and non-coal tar colors; and procedures for filing objections and requesting public hearings on regulations.

[fol. 156] Safety data which may be required under the regulations include detailed data from appropriate animal and other biological experiments; information as to chemical identity and composition and physical, chemical and biological properties; a description of tests, facilities and controls used in manufacture; data on stability, including a proposed expiration date where necessary; and, when needed, satisfactory methods for detecting and measuring the color in the products in which it would be used.

The regulations provide that a safety factor of 100 to 1 will ordinarily be used in applying animal experimentation data to man, unless use of a different factor is supported by the data submitted; and provide for taking into account any probable additive effect of the toxicity of the color with that of other related colors or with food additives or pesticides which may also be present in foods.

Where the data submitted do not establish safety for all uses of the color proposed, the new color law allows FDA to make allocations among competing needs. The regulations require the submittal of data by all interested parties before the allocations are made.

Provision is made for referral to an Advisory Committee upon request of the sponsor, where the Commissioner of Food and Drugs believes the data establish that the color additive is a cancer-producing agent which could not be permitted in any amount under the anti-cancer clause of the law. The Commissioner may upon his own initiative refer the matter to an Advisory Committee under similar circumstances. The Advisory Committee would be requested to study the data and report its conclusions and recommendations to the Commissioner within 60 days, unless an extension of time is authorized upon request of the Committee.

[fol. 157]

IN UNITED STATES DISTRICT COURT
U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration
Washington, D. C. 20201

FOR RELEASE TO COSMETIC TRADE PAPERS

Thursday, October 3, 1963

FDA's recent regulation limiting the exemption for hair dyes under the Federal Food, Drug, and Cosmetic Act applies immediately only to new hair dye formulations coming on the market, Commissioner of Food and Drugs George P. Larrick said today. Products currently being marketed will not be affected until June 22, 1965, Mr. Larrick said.

The statement was made in connection with an order in today's Federal Register dropping a former definition of a hair dye in FDA's color regulations.

The deleted regulation (21 CFR 1.200) was superseded by new regulations (Section 8.1(u)) published June 22, 1963, under the Color Additives Amendments of 1960.

The "hair dye" exemption applies to hair dyes which would otherwise be banned by the Act as containing poisonous or deleterious substances, provided the products bear specified caution labeling and adequate directions for patch testing.

FDA said that the patch test does not afford protection against all types of possibly harmful ingredients of hair dyes, and the new regulation limits the exemption to products for which the patch test would be meaningful.

The deletion of the former definition clears the record to avoid possible confusion, FDA said.

[fol. 158]

IN UNITED STATES DISTRICT COURT

Section of House Report (H. R. No. 1761, 6/7/1960, pp. 8-10) Stating the Need for Color Additive Legislation.

NEED FOR LEGISLATION

The principal reasons which give rise to the need for this legislation may be summarized as follows:

1. The law with respect to coal-tar colors—and this comprises most synthetic colors—is not in consonance with modern concepts of consumer protection, in that it does not allow the Secretary of Health, Education, and Welfare to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. For food, and for drugs and cosmetics other than those externally applied, the Secretary must ban the use of such a color completely, as not being "harmless," if it is found to be toxic in the laboratory when fed to animals in some concentrations, even though its actual level and manner of use may be completely safe. For externally applied drugs and cosmetics, the same principle applies if toxicity appears

in the laboratory in some concentrations by any relevant type of test, even though its actual level and manner of use may be wholly safe.

Prior to delisting proceedings by the Department of Health, Education, and Welfare there were 19 colors listed for unrestricted use in food, drugs, and cosmetics, 69 colors listed for unrestricted use in drugs and cosmetics, and 30 colors listed for use only in externally applied drugs and cosmetics, a total of 118 straight colors listed for certification. Seven colors have been removed from the food, drug, and cosmetic list and have been relisted for external use in drugs and cosmetic colors, so that we now have 12 food, drug, and cosmetic colors, 69 unrestricted drug and cosmetic colors, and 37 drug and cosmetic colors for external use. The Department has proposed that other colors be removed from listing and certification.

The principle of allowing colors to be used under tolerance limitations was endorsed, in 1956, by a committee of recognized scientists appointed by the National Academy of Sciences to review the coal-tar color research program [fol. 159] of the Food and Drug Administration, as indicated by the following excerpt from the Committee's report:

This Committee feels compelled to indicate that certification of a compound as "harmless and suitable for use" in food, drugs, and cosmetics as required under present law is unrealistic unless the level of use is specified (Report of the National Academy of Sciences-National Research Council Ad Hoc Advisory Committee To Review the Food and Drug Administration's Research Program on Coal-tar Dyes, June 1956).

2. The theoretically "perfect" public health protection once thought to be accorded by the present law regarding coal-tar colors has turned out to be in fact inadequate. While, theoretically, only "harmless" colors may be listed, a retesting program of the Food and Drug Administration, employing the most modern testing techniques, has led to the discovery that many of the so-called colors on the list

may in fact be toxic in some concentrations. Yet, the Secretary of Health, Education, and Welfare cannot take a particular color off the list until he establishes its toxicity by laboratory tests, a process which for the list as a whole may take as much as 20 years. Under the bill, there would, in general, be a maximum of $2\frac{1}{2}$ years during which the retesting process for the established colors would have to be completed—primarily by industry—and during which the Secretary could establish temporary tolerance limitations, at zero level if necessary, to protect the public health. This maximum period could be extended only where, in a particular case, such extension is necessary to complete the required safety tests for a color and is found consistent with protection of the public health.

3. There is a need for making applicable to all color uses and all types of color—whether they be coal-tar colors or others—the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At present [fol. 160] there are no provisions for the certification of non-coal-tar colors. There is, moreover, no pretesting requirement for non-coal-tar color additives as such, other than food additives.

4. Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting

the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which the Secretary of Health, Education, and Welfare believes could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use (including tolerance limitations and certification requirements) established by the Department of Health, Education, and Welfare.

The scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive has recently been approved by Congress [fol. 161] in temporary emergency legislation (Public Law 86-2) with respect to one coal-tar color, i.e., citrus red No. 2 for use in coloring mature oranges, after previous adoption of the "safe-for-use" principle in the Food Additives Amendment of 1958 (Public Law 85-929). In reporting upon the emergency legislation for citrus red No. 2, this committee said:

It is specifically provided that the provisions of this bill will become inoperative on August 31, 1961, or before that time if general legislation affecting coloring materials for food is enacted by the Congress. The reason for the time limit is that this is emergency legislation, which will meet the immediate needs of the citrus industry without permanently engrafting on the basic Food, Drug, and Cosmetic Act a new principle of tolerances for coal-tar colors which is not applicable to foods generally. The expiration date has been so fixed as to allow the Congress ample time to consider the application of this principle to all foods.

It is the intention of the committee as soon as feasible to study amendments to the Federal Food, Drug, and Cosmetic Act dealing with color additives generally, since the need for such legislation has been amply demonstrated to this committee (86th Cong., 1st sess., H. Rept. 88).

The bill—by permitting, for a reasonable period, the provisional listing and certification of heretofore commercially established colors, under temporary tolerances where necessary for public-health protection, pending the development of the scientific data required for a definitive determination as to the listing of these colors under the permanent provisions of the bill—would permit an orderly transition to the control procedures of the bill. At the same time, the bill would establish on a permanent basis a sound system of color regulation fully protective of consumer interests.

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[fol. 162]

IN UNITED STATES DISTRICT COURT

*Provisions of H. R. 11582 for Premarketing Clearance of
Cosmetics and Repeal of Hair Dye Exemption.*

87TH CONGRESS

2D SESSION

H. R. 11582

IN THE HOUSE OF REPRESENTATIVES

MAY 3, 1962

Mr. HARRIS introduced the following bill, which was referred
to the Committee on Interstate and Foreign Commerce

A BILL

To protect the public health by amending the Federal Food,
Drug, and Cosmetic Act to require a premarketing show-
ing of the safety of cosmetics; assure the safety, efficacy,
and reliability of therapeutic, diagnostic, and prosthetic
devices; and amend the Act with respect to cautionary
labeling; and for other purposes.

• • • • •
TITLE I—PREMARKETING CLEARANCE OF COSMETICS
FOR SAFETY

Sec. 101. New cosmetics.

Sec. 102. Prohibited acts, and so forth.

Sec. 103. Repeal of special exemptions for hair dyes.

Sec. 104. Effective date and transitional provisions.
• • • • •

[fol. 163]

TITLE I—PREMARKETING CLEARANCE OF COSMETICS FOR SAFETY

NEW COSMETICS

SEC. 101. (a) Section 601, as amended, of the Federal Food, Drug, and Cosmetic Act (relating to cosmetics deemed adulterated) is further amended by adding at the end thereof the following new paragraph:

“(f) If it is unsafe within the meaning of section 605(a).”

(b) Chapter VI of such Act is amended by adding at the end thereof a new section as follows:

“SEC. 605. (a) A cosmetic shall be deemed unsafe for the purposes of section 601 (f) if—

“(1) its composition is such that such cosmetic is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of cosmetics, as having been adequately shown to be safe for its intended use and other reasonably foreseeable uses, or

“(2) its composition is such that such cosmetic, as a result of investigations to determine its safety for such a use, has become so recognized, but such cosmetic has not, otherwise than in such investigations, been so used to a material extent or for a material time,

unless an application with respect to such cosmetic has been filed pursuant to subsection (b) and there is in effect an approval of such application by the Secretary under this section, or unless such cosmetic is for investigational use and conforms to the terms of an exemption which is in effect pursuant to subsection (i).

[fol. 164] “(b) Any person may file with the Secretary an application for determination by the Secretary of the safety of any cosmetic described in clause (1) or (2) of subsection

(a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such cosmetic is safe for use; (2) a full list of the articles used as components of such cosmetic; (3) a full statement of the composition of such cosmetic; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such cosmetic; (5) such samples of such cosmetic and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such cosmetic.

• • • • • • •

REPEAL OF SPECIAL EXEMPTIONS FOR HAIR DYES

SEC. 103. (a) Paragraph (a) of section 601 of such Act is amended by striking out the colon which precedes "*Provided*" and all that follows down to but not including the period at the end of such subsection.

(b) Paragraph (e) of such section 601 is amended by striking out "it is not a hair dye and".

(c) Paragraph (e) of section 602 of such Act is amended by striking out the second sentence of such paragraph.

(d) Subsection (a) of section 706 of such Act is amended by striking out "other than a hair dye (as defined in the last sentence of section 601(a))".

[fols. 165-167]

Clerk's Note: "Order denying motion to dismiss and for summary judgment and certifying an immediate appeal" is omitted from the record here as it appears on pages 46-47 *supra*.

[fol. 168]

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

THE TOILET GOODS ASSOCIATION, INC., et al., Plaintiffs,

—v.—

ANTHONY J. CELEBREZZE, Secretary of Health, Education
and Welfare, and GEORGE P. LARRICK, Commissioner of
Food and Drugs, Defendants.

Before: Moore, Smith and Anderson, U.S.C.JJ.

ALLOWANCE OF MOTION FOR LEAVE TO APPEAL PURSUANT TO
28 U.S.C. §1292(b)—Filed January 10, 1966

Motion for leave to appeal pursuant to 28 U.S.C. §1292
(b) granted. Argument set for week of February 21, 1965.
Notice of appeal to be filed forthwith. Parties to agree on
time schedule for briefs; in the absence of agreement,
parties may confer with the court with respect thereto.

LPM, JJS by LPM, RPA by LPM, U.S.C.JJ.

January 10, 1966

[fol. 169]

[File endorsement omitted]

[fol. 170]

IN THE UNITED STATES COURT OF APPEALS

SECOND CIRCUIT

Present: Hon. Leonard P. Moore, Hon. J. Joseph Smith,
Hon. Robert P. Anderson, Circuit Judges.

THE TOILET GOODS ASSOCIATION, INC., et al.,
Plaintiffs-Appellees,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education
and Welfare, and GEORGE P. LARRICK, Commissioner of
Food and Drugs, Defendants-Appellants.

ORDER GRANTING MOTION FOR LEAVE TO APPEAL

—January 10, 1966

A motion having been made herein by counsel for The
Toilet Goods Association, Inc.; et al., for leave to appeal,

Upon consideration thereof, it is

Ordered that said motion be and it hereby is granted and
that the notice of appeal shall be filed forthwith.

Further ordered that the argument of the appeal be and
it hereby is set for the week of February 21, 1966.

Further ordered that the parties shall agree on a time
schedule for briefs or that in the absence of agreement,
the parties may confer with the court with respect thereto.

A. Daniel Fusaro, Clerk.

[fol. 171]

[File endorsement omitted]

[fol. 172]

IN THE UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 325—September Term, 1965.

Argued February 25, 1966

Docket No. 30261

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.;
 AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE
 BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.;
 CHESEBROUGH-POND'S INC.; CHRISTIAN DIOR PERFUMES
 CORP.; CLAIROL INCORPORATED; COLONIAL DAMES CO.,
 LTD.; COTY, INC.; FABERGE INC.; FRANCES DENNY, INC.;
 THE FULLER BRUSH CO.; THE GEORGE W. LUFT CO.,
 INC.; THE GILLETTE COMPANY; A. M. HANSEN, doing
 business as HOUSE OF HOLLYWOOD; HARPER METHOD,
 INC.; HELENA RUBINSTEIN, INC.; HELENE CURTIS INDUS-
 TRIES, INC.; HENRY/HARAN/HUTCHINGS, INC.; HERBOLD
 LABORATORY, INC.; JOHN H. BRECK, INC.; KOLMAR LABO-
 RATORIES, INC.; LADY LENNOX COMPANY, INC.; LEHN &
 FINK PRODUCTS CORPORATION; ARNOLD L. LEWIS, doing
 business as STUDIO COSMETIC CO.; MAX FACTOR & CO.;
 MAYBELLINE CO.; MERLE NORMAN COSMETICS, INC.; JACK
 B. NETHERCUTT, doing business as NETHERCUTT LABORA-
 TORIES; NEUTROGENA CORP.; NUTRILITE PRODUCTS, INC.;
 OLD 97 COMPANY; PRIVATE LABEL COSMETICS CO., INC.;
 PURITAN COSMETICS CO.; REVLON, INC.; ROUX LABORA-
 [fol. 173] TORIES, INC.; SHULTON, INC.; and YARDLEY OF
 LONDON, INC., Plaintiffs-Appellees,

—v.—

JOHN W. GARDNER, Secretary of Health, Education and
 Welfare, and JAMES L. GODDARD, Commissioner of Food
 and Drugs, Defendants-Appellants.

Before: Waterman, Moore and Friendly, Circuit Judges.

Appeal by the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs from an order of the District Court for the Southern District of New York, Harold R. Tyler, Jr., Judge, denying their motion to dismiss or grant summary judgment in an action for a declaration of invalidity of four Food and Drug Administration regulations relating to color additives. Affirmed as to Counts 1, 2 and 3; reversed as to Count 4.

Arthur S. Olick (Robert M. Morgenthau, United States Attorney for the Southern District of New York; James G. Greilsheimer, Assistant United States Attorney, of Counsel), for Defendants-Appellants.

Edward J. Ross (Breed, Abbott & Morgan, New York, N. Y.; Stephen R. Lang, of Counsel), for Plaintiffs-Appellees.

[fol. 174]

OPINION—Decided April 13, 1966

Friendly, Circuit Judge:

In July 1960, Congress added to the Federal Food, Drug, and Cosmetic Act a number of new provisions known as the Color Additive Amendments, 74 Stat. 397, 21 U.S.C. §§321-376. These were intended

“to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerance, under which such additives may be safely used.” H. R. Rep. No. 1761, 86th Cong., 2d Sess., 1960 U. S. Code Cong. & Ad. News 2887.

The Commissioner of Food and Drugs, to whom the Secretary of Health, Education and Welfare has delegated the Department's functions under the Act, 22 F. R. 1051 (1957), 25 F. R. 8625 (1960), held rule-making proceedings conforming to §4 of the Administrative Procedure Act, 5 U. S. C. §1003, and issued Color Additive Regulations, 21

C. F. R. Part 8, effective, with certain exceptions, on June 22, 1963.

The following November the Toilet Goods Association, a trade organization of cosmetic manufacturers whose members allegedly represent 90% of annual United States sales, and forty manufacturers and distributors of cosmetics brought this action against the Secretary and the Commissioner in the District Court for the Southern District of New York for a declaratory judgment that four provisions of the Regulations exceeded the authority conferred by the statute. Jurisdiction was properly predicated on 28 U. S. C. §§1331 and 1337. See *Smith v. Kansas [fol. 175] City Title & Trust Co.*, 255 U. S. 180 (1921).¹ The defendants moved to dismiss or to strike certain portions of the complaint on various grounds, among others that the case was inappropriate for declaratory relief and that the action was an unconsented suit against the sovereign; plaintiffs cross-moved for summary judgment. In November 1964 Judge Tyler denied both motions in an opinion, 235 F. Supp. 648, relying in part on *Abbott Labs v. Celebrezze*, 228 F. Supp. 855 (D. Del. 1964), where the court had granted a declaratory judgment invalidating labeling regulations under the same statute. A year later, when the case was nearly ready for trial, the Secretary and the Commissioner renewed their motion to dismiss on the two grounds stated, arguing that a different conclusion on "the issue of justiciability" was called for by the Third Circuit's

¹ We thus do not reach the question whether §10 of the Administrative Procedure Act, 5 U. S. C. §1009, constitutes an affirmative grant of jurisdiction with respect to the review of federal administrative action, as the Supreme Court apparently assumed in *Rusk v. Cort*, 369 U. S. 367, 371-72 (1962) and we recently did in *Cappadora v. Celebrezze*, — F. 2d — (2 Cir. 1966). But see *Ove Gustavsson Contracting Co. v. Floete*, 278 F. 2d 912 (2 Cir.), cert. denied, 364 U. S. 894 (1960). Since 28 U. S. C. §§1336-40 do not require a jurisdictional amount, this question arises only in cases such as social security, passport and citizenship matters, where none of these sections is applicable and the jurisdictional amount required by §1331 is not met.

reversal of the *Abbott Laboratories* decision, 352 F. 2d 286 (1965),² and the District of Columbia Circuit's recent holding that declaratory relief was not available to challenge certain regulations adopted under the Tobacco Inspection Act, 7 U. S. C. §714(b), *Danville Tobacco Ass'n v. Freeman*, 351 F. 2d 832 (D. C. Cir. 1965). Judge Tyler adhered to his determination but, at the defendants' request, made the necessary certification for an application to prosecute an [fol. 176] interlocutory appeal under 28 U. S. C. §1292(b); permission to appeal was granted by a panel of this court.

I.

The first two counts of the complaint charge that the Regulations exceed the authority conferred by the statute in treating finished cosmetic products and all diluents—unpigmented materials with which colors are mixed—as “color additives” subject to various requirements for testing and administrative certification. The basic section of the Color Additive Amendments is §706 of the Act, 21 U. S. C. §376, which provides that a “color additive” shall be deemed unsafe unless it meets two conditions:³ The additive must be covered by a “regulation,” issued by the Secretary on a finding of suitability, which lists it for use either generally or under prescribed conditions; and it must either come from a batch certified for such use by the Secretary under appropriate regulations or have been exempted from the certification requirement.

The term “color additive,” on which the controversy turns, is defined in §201(t)(1), as a material which

(A) is a dye, pigment, or other substance made by a process of synthesis . . . or otherwise derived . . . from a vegetable, animal, mineral, or other source, and

² Subsequent to the argument of this appeal, certiorari was granted, 34 U. S. L. Week 3294 (March 1, 1966) (No. 824).

³ This is subject to an exception, not here important, for color additives covered by an exemption for investigational use by qualified experts, 21 U. S. C. §§376(a)(2) and (f).

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto.

21 U. S. C. §321(t)(1)

[fol. 177] The Regulations of the Food and Drug Administration (FDA) interpret the statutory definition of color additive as including "all diluents" and state further that

A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." Reg. §8.1(f).

The term "diluent" is defined as:

any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

Reg. §8.1(m)

The manufacturers admit that the coloring ingredient in a cosmetic is a "color additive" fully subject to both listing and certification requirements of §706, and that a "diluent," in what they insist is the accepted definition of an inert substance used to dilute dyes and pigments, is subject to the Secretary's power to certify additives "with safe diluents or without diluents," §706(c). They complain,

however, that the Regulations' comprehensive definition of "color additive" goes beyond the reach of the statute in imposing both listing and certification requirements on finished products—like lipstick, nail polish, etc.—and non-[fol. 178] color ingredients that were never intended to be subject to premarketing clearance, and on traditional diluents that were meant to be subject only to certification as components of dyes and pigments.

The third count of the complaint relates to provisions in the Regulations which attempt to subject hair dye products to premarketing clearance in what is alleged to be violation of the exemption recognized in the statute. The Act as passed in 1938, in defining those cosmetics that were deemed to be adulterated, contained in §601(a) an explicit exemption for hair dyes:

This provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing.

52 Stat. 1054

The exemption was carried forward in §601(e) which declared that a cosmetic should be deemed adulterated "If it is not a hair dye and it bears or contains a coal-tar color other than one" from a certified batch. When Congress revised the statute in the 1960 Amendments, it left §601(a) as it was but modified §601(e) to read "If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe" within the meaning of §706.

The Regulations recognized the statutory exemption where proper labeling called for use of the patch test but,

armed with an expansive definition of "color additive" in [fol. 179] §8.1(f) which would on its face seem to include in a preparation for use on the hair any coloring ingredient as well as the finished product, proceeded to limit the exemption as follows:

"The hair dye" exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious substance in the "hair dye" is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.

Reg. §8(u)

The manufacturers claim that the Regulations go beyond the statute in several ways: Whereas the 1938 Act literally exempted from premarketing clearance any coal-tar hair dye complying with the statutory condition of notice and the amendments did not purport to effect any change, the Regulations grant exemption only if the color additive in the hair dye substance is one whose irritating qualities would be detected by a patch test; and, contrary to the longstanding interpretation—in effect by regulation when

[fol. 180] the amendments were adopted⁴—which applied the exemption in its full scope to dual-purpose hair products like shampoos, rinses and tints with a coal-tar coloring component, the Regulations seem to limit the exemption to the coloring ingredient itself.

Count 4 of the complaint attacks a section of the Regulations, §8.28(a)(4), which states that when it appears to the Commissioner that a person has refused to permit duly authorized employees of the FDA “free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived,” he may suspend certification service to such person until adequate corrective action is taken. The first sentence of §704(a) of the Act, applicable to all goods, drugs, devices, or cosmetics subject thereto, authorizes the Secretary to inspect any “factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labelling therein”; the second sentence, dealing only with places where prescription drugs are manufactured, processed or held, provides for inspection extending “to all things therein (including records, files, papers, processes, controls, and facilities).” The manufacturers say the challenged regulation illegally extends to cosmetics the broadened inspection authorized only for prescription drugs, and improperly subjects trade secrets to exposure.

The expanded definition of “color additives,” the narrowing of the hair dye exemption and the allegedly compelled disclosure of secret formulae and processes impose, the [fol. 181] manufacturers claim, burdens not contemplated by the statute and threaten immediate and irreparable injury. Even though coloring ingredients have been prop-

⁴ Reg. §1.200 apparently defined the term “coal-tar hair dye” in the §601(a) exemption to include “all articles containing any coal-tar color.” This definition of hair dyes was deleted by the Commissioner as superseded by §8.1(u) of the Color Additive Regulations. 28 F. R. 10638 (1963).

erly pretested, listed and certified in compliance with the statutory clearance scheme, the regulations require filing a separate listing application for each finished product, traditional diluent and non-color ingredient, including those formerly exempted under the hair dye provision; each application must be accompanied by a \$2600 filing fee, Reg. §8.50(c), and supported by extensive scientific tests establishing suitability for intended use, Reg. §3.4(c). Even after listing, every ingredient and finished product must come from a certified batch unless the Secretary has granted an exemption; a minimum fee of \$100 is charged for each certification, Reg. §8.51(a). An affidavit by one manufacturer claimed that the listing of its finished products alone for the issuance of regulations would entail filing fees of \$7,000,000 and testing costs of nearly \$42,000,000, and that certification fees for a single year would amount to \$750,000.⁵ Beyond such out-of-pocket costs, increased by substantial additional expenses for record-keeping compliance with the challenged regulations, by requiring significant changes in established business practices and curtailing distribution of new products, allegedly would cause major and costly disruption of the cosmetic industry. Moreover, the disclosure of formulae and processes necessary to meet the new listing requirements and to avoid loss of certification for refusing inspection allegedly would result in misappropriation of trade secrets and discourage research and development of improved cosmetic products.

[fol. 182] Failure to comply with the challenged regulations could have serious consequences if they are valid. Under §601 of the Act, a cosmetic other than a hair dye is deemed adulterated if "it is, or it bears or contains, a color additive which is unsafe" within the meaning of §706(a). Projection of any adulterated article into the stream of

⁵ Very likely these figures are exaggerated since they take no account either of the FDA's power to require information on diluents as a condition of approving coloring ingredients and granting certification or of the likelihood of exemption from certification.

interstate commerce and refusal to allow inspection required by §704 are prohibited acts under the statute, and are subject to injunction and entail criminal liability, §§301-303; and any adulterated article may be seized under §304. The manufacturers say that, apart from all else, the publicity incident to criminal or civil proceedings against them for failure to comply with the Regulations would be seriously detrimental in a highly competitive industry which spends millions in cultivating public good will and is dependent on consumer confidence in the integrity of its products.

The Secretary and the Commissioner respond that the fears as to the dilemma posed by the Regulations are exaggerated. They insist that the Regulations merely expound the manner in which they intend to construe the amendments, ~~that nothing has yet been done to apply the provisions of which plaintiffs complain~~, and that ample opportunity to test the Regulations in concrete fact situations is afforded by the path for review spelled out in the statute. If the manufacturers will only comply with the listing and certification requirements, the FDA's application of the statute will, under §706(d), be subject to the general administrative provisions on hearings and review in §701. Since the review authorized in §706(d) is directed at decisions approving or disapproving listing and certification and §§701(e) and (f) are limited to review of other specifically enumerated agency determinations, the contention is not that the statutory provisions afford a direct path to [fol.183] review of the general regulations on listing requirements; it is rather that they furnish an indirect but nevertheless sufficient one which the manufacturers ought to have taken. The proper course, defendants say, is for a manufacturer to petition for the listing of diluents and finished cosmetic products as color additives, while protesting against the need for doing so and conforming with the detailed requirements for filing information only to the extent he believes proper under the statute; such a

petition could be accompanied by a request for exemption from batch certification, again with appropriate protest and non-compliance with the requirement of factual data to support the application. Either the FDA would retreat from applying its announced interpretation of the statute and grant the petition and the request for exemption, or it would deny them in which event the road to a court of appeals would be open under §§701(e) and (f).

II.

The serious questions⁶ are whether direct challenge of the Regulations by suit in a district court is impliedly barred by the availability of review of listing and certification denials in a court of appeals, and whether the controversy is appropriate for judicial determination prior to application of the Regulations in a particular factual situation.

[fol.184] We are not persuaded that by providing a procedure for review of certain administrative decisions under the Food and Drug Act in the courts of appeals, Congress meant to foreclose relief with respect to other agency action under the Administrative Procedure Act §10, 5 U. S. C. §1009, or the Declaratory Judgment Act, 28 U. S. C. §2201, in a case where this would otherwise be appropriate. The agency determinations specifically reviewable under §701(e) relate to such technical subjects as chemical properties of particular products and the formulation and application of safety standards for pro-

⁶ We need not discuss in the text the surprising contention that an action for a declaration that federal regulatory officers have acted in excess of their authority constitutes an unconsented suit against the United States. The contrary is clearly established by *Philadelphia Co. v. Stimson*, 223 U. S. 605, 619-20 (1912), see *Stark v. Wickard*, 321 U. S. 288, 290 (1944), and indeed follows inevitably from *Ex parte Young*, 209 U. S. 123 (1908); law officers of the Government ought not to take the time of busy judges or of opposing parties by advancing an argument so plainly foreclosed by Supreme Court decisions.

tecting public health; Congress naturally did not wish courts to consider such matters without the benefit of the agency's views after an evidentiary hearing before it. Section 701, however, also contemplated other less specialized administrative action by authorizing, in subsection (a), the making of regulations for the efficient enforcement of the statute, and it expressly declared in subsection (f) that the provision for review of certain orders in the courts of appeals was "in addition to and not in substitution for any other remedies provided by law." 21 U. S. C. §371(f)(6). The section as a whole does not indicate to us any congressional intent either to insulate administrative action not covered by subsection (e) from challenge as in excess of statutory authority, see *Stark v. Wickard*, 321 U. S. 288, 308-11 (1944); cf. *Cappadora v. Celebrezze*, 356 F. 2d 1, 5 (2 Cir. 1966), or to postpone immediate challenge to such action where awaiting the issuance of adjudicative orders subject to statutory review would provide less effective relief.⁷ Insofar as *Abbott* [fol. 185] *Labs. v. Celebrezze*, 352 F. 2d 286, 289 (3 Cir. 1965), cert. granted, intimates otherwise, we are unwilling to follow it.

⁷ The legislative history of the 1938 Act suggests that Congress had no intention of limiting review of other action by adopting a special procedure for the enumerated determinations. The House Report, referring to the savings clause in §701(f)(6), stated:

There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.

H. R. Rep. No. 2139, 75th Cong., 3d Sess., p. 11 (April 14, 1938).

The accompanying minority report, in endorsing the Secretary's challenge to the new review provisions as jeopardizing enforcement of the statute, indicated that the special procedure was understood to be an additional protection for industry and not an exclusive method of review of all actions for the benefit of the agency. H. R. Rep. 2139, Pt. 2 (April 21, 1938).

The question whether a plaintiff may obtain judicial relief in cases like this has been variously phrased as whether he has "standing" to challenge the administrative action as a person "suffering legal wrong" or "aggrieved" within the meaning of §10 of the APA, whether the dispute is an "actual controversy" within the Declaratory Judgment Act, or whether it is sufficiently "ripe" for resolution by the courts. See Jaffe, *Judicial Control of Administrative Action* 395-98 (1965). In fact, the critical issue is apt to be less a matter of standing or of actual controversy than of the advisability of reviewing an administrative rule prior to its application in a specific factual situation. The current healthy trend toward implementing agency policy by rule-making cuts both ways with respect to declaratory relief—increasing the need for this sort of assistance on the part of those subjected to such rules, see *Columbia Broadcasting Sys., Inc. v. United States*, 316 U. S. 407, 421 (1942), but also creating a danger that, unless the courts are circumspect, administration may be improperly halted, at least temporarily, before it has gotten the slightest start.⁸ The problem is not to be solved, as the [fol. 186] parties suggest, by applying some readily procurable litmus paper which will determine whether a controversy is "justiciable"; what is required, as in the case of challenge to the constitutionality of a statute, is a reasoned evaluation of "both the appropriateness of the issues for decision by courts and the hardship of denying judicial relief." *Joint Anti-Fascist Refugee Comm. v. McGrath*, 341 U. S. 123, 156 (1951) (Frankfurter, J., concurring); see Jaffe, *supra*, at 396, 423.

⁸ The danger of unwarranted postponement of the effectiveness of agency action is augmented by the fact that a suit for declaratory relief must be brought in a district court, twice removed from the supreme tribunal, whereas adjudicative orders are generally reviewable either in courts of appeals or in specially constituted district courts from which appeal lies directly to the Supreme Court. Yet here too there is another side; a district court may be in a better position than a court of appeals to carry out fact finding, as Congress recognized in the Hobbs Act, 5 U. S. C. §1037(b).

The appropriateness of passing judgment on the validity of an administrative regulation prior to its application to particular facts depends on such factors as how far the rule represents the definitive position of the agency and the extent to which the challenge raises a clearcut legal issue susceptible of judicial solution without reference to fact variables arising in its implementation. Cf. *Northeast Airlines, Inc. v. CAB*, 345 F. 2d 662, 664 (1 Cir. 1965). Review might be considered premature where an agency rule had not received substantially as full consideration in its formulation as it would have in subsequent application, or where future experience would be likely to result in significant modifications as to its precision or scope. Judicial determination might also be deemed inappropriate where the controversy over the rule did not present a legal issue that a court was qualified to resolve without reference to factual determinations more effectively made by the agency familiar with day to day administration. See Jaffe, *supra*, at 406. In this case, however, the Regulations under [fol. 187] attack were issued after a full hearing with notice and by their terms represent the definitive agency position on the reach of the statutory requirements for listing and certification of cosmetics; see *Columbia Broadcasting Sys., Inc. v. United States*, *supra*, 316 U. S. at 422; *United States v. Storer Broadcasting Co.*, 351 U. S. 192, 198 (1956); to the extent that they purport to apply pre-marketing requirements to broad categories like finished products and noncoloring ingredients and define the hair-dye exemption, they appear, *prima facie*, to be susceptible of reasoned comparison with the statutory mandate without inquiry into factual issues that ought to be first ventilated before the agency. Indeed, it is manifest that if the manufacturers adhere to their legal position, *pro forma* individual applications to the FDA for listing and certification would produce a record no more, and very likely less, illuminating than what the district court will develop at trial of this action in which the great bulk of the industry is represented and will be bound. The mere

fact that the procedure which the defendants suggest would bring the issue directly to a court of appeals without prior resort to a district court, while entitled to some weight, is not controlling. As indicated earlier, the statutory procedure for review of individual determinations in the courts of appeals was not intended as a means for challenging FDA rule-making of the usual sort; as shown by the authorities discussed below, the mere fact that pursuit of that course could produce a decision on legal issues similar to that here sought does not make its use mandatory.

With respect to the other relevant consideration, the degree of hardship warranting declaratory relief, although some older precedents suggest broadly that an administrative ruling is not reviewable until and unless it imposes an [fol. 188] obligation or subjects the plaintiff to some civil or criminal liability, see, e.g., *United States v. Los Angeles & Salt Lake R.R.*, 273 U. S. 299, 309-10 (1927); *Shannahan v. United States*, 303 U. S. 596, 599 (1938), there has been a growing recognition that the timeliness of review depends on a broader concept of the substantiality of present or immediate harm. See 3 Davis, *Administrative Law Treatise* §2107 (1958). In *Columbia Broadcasting Sys., Inc. v. United States*, 316 U. S. 407, 417-21 (1942), the Supreme Court declared that though a particular rule does not of itself deny a license or directly impose sanctions, it may nevertheless be reviewable if it establishes a general standard of conduct which by its very promulgation demands conformity and poses, for the plaintiff or others with whom he must deal, the alternatives of compliance or severe penalties of forfeiture or disruption of business operations. In *Frozen Food Express v. United States*, 351 U. S. 40, 43-44 (1956), the Court recognized that an agency order generally announcing the scope of administrative regulation was subject to immediate frontal attack, although opportunities for later challenge were sure to come from a cease and desist order by the ICC, see *Eastern Texas Motor Lines v. Frozen Food Express*, 351 U. S. 49 (1956),

or suit for an injunction by the agency or competitors.⁹ And in *United States v. Storer Broadcasting Co.*, 351 U. S. 192, 199-200 (1956), declaratory rules setting limits on the number of licenses to be granted for broadcasting stations under common ownership were held to be immediately reviewable because they operated "to control the business affairs" of the plaintiff and made it impossible to "cogently plan its present or future operations" so long as their [fol. 189] validity remained undetermined; direct challenge to the regulations was permitted even though review might have been obtained by provoking an adverse administrative order, see 351 U. S. at 208 (dissenting opinion).¹⁰ See also *Flemming v. Florida Citrus Exch.*, 358 U. S. 153, 168 (1958).

We see little profit in debating the point, much discussed by the parties, whether the Regulations are "interpretative" or "legislative." Although that issue would have to be faced if the FDA had failed to comply with the rule-making procedures of §4 of the APA because of a claim

⁹ If it be said that the carrier was subject to liability for criminal penalties even before a cease and desist order, or an injunction, the same is true here.

¹⁰ In fact the FCC dismissed the plaintiff's application for an additional station on the basis of the new rules the very day they were adopted, 351 U. S. at 197, but review of the particular decision was not sought.

We recognize that in *Storer* review of the rule was in the Court of Appeals for the District of Columbia, the same tribunal to which *Storer* would have gone for review of the denial of an application; but the dissenters thought the rationale of the majority would support a suit for declaratory relief in a district court after the 60-day limitation for seeking review by the Court of Appeals had expired, 351 U. S. at 210 (dissenting opinion of Harlan, J.). A more important differentiating consideration may be that awaiting denial of a future application may not have afforded a broadcaster who had reached the ceiling so full an opportunity for challenge as might appear at first blush; if the application was a competitive one for a new license, the FCC might predicate denial on other grounds, and to negotiate a transfer of an existing license in the teeth of the multiple-ownership rules would be of dubious business practicability. However, this ground for distinguishing *Storer* would not apply to *Frozen Food Express*.

on its part that the Regulations were merely "interpretative," the interpretative character of a regulation does not necessarily make it unripe for review; we perceive no reason why a rule whereby an agency subjects to regulation activities contended to be immune should be exempt from immediate review because it purports to interpret a statute although it would not be if made in the exercise, contended to be illegal, of a substantive rule-making power. See *Frozen Food Express v. United States*, *supra*; Jaffe, Ju- [fol. 190] dicial Control of Administrative Action 405-07 (1965); and 1 Davis, Administrative Law Treatise §5.03 (1965 Pocket Part), criticizing on this ground *American President Lines, Ltd. v. FMC*, 316 F. 2d 419 (D. C. Cir. 1963), on which defendants rely. Neither do we think anything is to be gained by an attempt at comprehensive review of the decisions; the many cases in this area are not truly reconcilable and the law has been moving in the direction of greater freedom of review, see Jaffe, *supra*, at 412-17 (which, *inter alia*, criticizes another decision relied on by defendant, *Helco Prods. Co. v. McNutt*, 137 F. 2d 681 (D. C. Cir. 1943)), and 3 Davis, Administrative Law Treatise §§21.06-21.08 (1958). We limit ourselves to the two recent Court of Appeals decisions which defendants most strongly urge upon us.

Danville Tobacco Ass'n v. Freeman, 351 F. 2d 832 (D. C. Cir. 1965), was a rather weak case for declaratory relief. The plaintiffs there were neither threatened with penalties nor, like those in *Frozen Food* and here, faced with the need of applying for licenses to permit continuation of an established business; moreover, there was no showing that the challenged regulation was in fact preventing expansion of their operations, since they had filed no applications and petitions by other applicants had been denied on grounds other than those attacked. Agreeing with the defendants that *Abbott Labs. v. Celebrezze*, 352 F. 2d 286 (3 Cir. 1965), cert. granted, is not distinguishable on any satisfying basis, we must confess, with all respect, our inability to understand why the plaintiffs there should be required to violate

the challenged FDA regulation in order to raise the same legal issue as to which the district court had granted declaratory relief. Insofar as the *Abbott* decision rested on a negative implication from the limited review provisions of [fol. 191] the Food and Drug Act, we have already noted our inability to agree.

III.

In applying the general considerations thus developed to the precise issues here presented, we must bear in mind that this appeal is not from a declaratory judgment but from the denial of a motion to dismiss a complaint seeking one. The issue on such an appeal is not whether the grant of a declaratory judgment was in fact appropriate but whether it so clearly would not be that dismissal *in limine* was required.

As regards the counts of the complaint challenging the inclusion of finished products and color additives and the alleged restrictions of the hair-dye exemption, the appeal must fail. These Regulations appear to have an immediate impact on the industry, posing the unacceptable alternatives of complying or of incurring possible forfeitures and criminal liability, and calling into question long standing practices of premarketing testing and clearance. The issues framed by the counts of the complaint addressed to these Regulations appear sufficiently suitable for immediate judicial resolution and the threatened harm sufficiently great, that the district court properly declined to dismiss them. If the court should find that the issues are not susceptible of resolution without detailed factual evidence that ought to be first sifted by the agency, or that measures being taken by the FDA for the listing and exemption from certification of approved diluents have so reduced the hardship on the plaintiffs as to make declaratory relief inappropriate, it need not proceed to judgment. But, so far as we can now see, the sooner the industry's claims as to the coverage of the Act in these respects are determined, the better for everybody. As said in *Jaffe*, Judicial Review of

[fol. 192] Administrative Action 404 (1965), "The public has an interest in early implementation of policy; the regulated person has a legitimate interest whether to plan or not to plan his operation." Moreover, the party disappointed by court decision may wish to take the case to Congress.

The fourth count of the complaint, relating to agency inspection of formulae and processes, stands differently. Here the challenged regulation, §8.28(a)(4), does not of itself demand compliance at the expense of penalties. A manufacturer who refuses access to his trade secrets is not threatened with criminal liability or seizure; the regulation does not suggest that such refusal will be deemed a "prohibited act" under the statute, as it would be in the case of prescription drugs. It simply warns the industry that the Commissioner may—not that he inevitably will—consider a refusal to permit such inspection a sufficient cause for suspending certification. Moreover, the next paragraph, §8.28(b), says that upon receipt of notice of suspension, the person so notified may request a hearing upon the factual basis therefor. If after such hearing the Commissioner should adhere to his refusal to certify, review by a court of appeals would seem available under §§706(d) and 701(f); if not, an action could be brought in the district court.

In this instance the possibility of unlawful injury to the plaintiffs is, on its face, too remote for declaratory relief. No one can now say whether the Commissioner will ever make a demand for free access to color additive processes or formulae, whether any manufacturer will ever decline this, what the Commissioner would do if so refused, and what result a hearing would have. The fact that the Commissioner's proclamation of the possible consequences of refusal may induce manufacturers to be more compliant [fol. 193] than if he had kept silent until an episode calling for action arose is not a sufficient basis for declaratory relief. Moreover, it is impossible to see what declaration a court could properly make. No one could reasonably assert that circumstances warranting suspension of certification if a manufacturer refused to give the FDA information

concerning processes or formulae could never arise; Congress' failure to empower the agency to compel an inspection of processes or formulae is not a mandate to grant certificates when the public cannot properly be protected otherwise. Review of this Regulation should be on a case by case basis and with a factual record to assist in determining whether access to secret processes and formulae is necessary and appropriate to performance of the task of effective premarketing clearance in a particular instance—at least in the absence of experience showing consistent abusive tactics.

The judgment with respect to Count 4 is reversed with instructions to grant the motion to dismiss; the judgment with respect to Counts 1, 2 and 3 is affirmed, with further proceedings to be promptly taken in the district court in accordance with this opinion.

[fol. 194]

IN THE UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Present: Hon. Sterry R. Waterman, Hon. Leonard P. Moore, Hon. Henry J. Friendly, Circuit Judges.

THE TOILET GOODS ASSOCIATION, INC., et al.,
Plaintiffs-Appellees,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, Defendants-Appellants.

JUDGMENT—April 13, 1966

Appeal from the United States District Court for the Southern District of New York.

This cause came on to be heard on the transcript of record from the United States District Court for the Southern District of New York, and was argued by counsel.

On Consideration Whereof, it is now hereby ordered, adjudged, and decreed that the order of said District Court be and it hereby is affirmed as to the First, Second and Third Counts of the complaint.

It is further ordered that the order of said District Court be and it hereby is reversed as to the Fourth Count of the complaint with instructions to grant the motion to dismiss in accordance with the opinion of this court.

A. Daniel Fusaro, Clerk.

[fol. 195]

[File endorsement omitted]

[fol. 196] Clerk's Certificate to foregoing transcript (omitted in printing).

[fol. 197]

SUPREME COURT OF THE UNITED STATES

No. —October Term, 1966

SECRETARY OF HEALTH, EDUCATION AND
WELFARE, et al., Petitioners,

vs.

TOILET GOODS ASSOCIATION, INC., et al.

ORDER EXTENDING TIME TO FILE PETITION FOR
WRIT OF CERTIORARI—July 7, 1966

Upon Consideration of the application of counsel for
petitioner(s),

It Is Ordered that the time for filing a petition for writ
of certiorari in the above-entitled cause be, and the same
is hereby, extended to and including August 11, 1966.

Potter Stewart, Associate Justice of the Supreme
Court of the United States.

Dated this 7th day of July, 1966.

[fol. 198]

SUPREME COURT OF THE UNITED STATES

No. 336—October Term, 1966

THE TOILET GOODS ASSOCIATION, INC., et al., Petitioners,

v.

JOHN W. GARDNER, Secretary of Health,
Education and Welfare, et al.

ORDER ALLOWING CERTIORARI—October 10, 1966

The petition herein for a writ of certiorari to the United States Court of Appeals for the Second Circuit is granted, and set for oral argument immediately following No. 39. The case is consolidated with No. 438 and a total of one hour is allotted for oral argument.

And it is further ordered that the duly certified copy of the manuscript of the proceedings below which accompanied the petition shall be treated as though filed in response to such writ.

Mr. Justice Brennan took no part in the consideration or decision of this petition.

[fol. 199]

SUPREME COURT OF THE UNITED STATES

No. 438—October Term, 1966

JOHN W. GARDNER, Secretary of Health, Education,
and Welfare, et al., Petitioners, D

v.

THE TOILET GOODS ASSOCIATION, INC., et al.

ORDER ALLOWING CERTIORARI—October 10, 1966

The petition herein for a writ of certiorari to the United States Court of Appeals for the Second Circuit is granted, set for oral argument immediately following No. 39. The case is consolidated with No. 336 and a total of one hour is allotted for oral argument.

And it is further ordered that the duly certified copy of the transcript of the proceedings below which accompanied the petition shall be treated as though filed in response to such writ.

Mr. Justice Brennan took no part in the consideration or decision of this petition.

7

No. **336**

JUL 12 1966

JOHN F. DAVIS, CLERK

Supreme Court of the United States

OCTOBER TERM, 1966

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.;
AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE BELL,
INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.; CHESE-
BROUGH-POND'S INC.; CHRISTIAN DIOR PERFUMES CORP.;
CLAIROL INCORPORATED; COLONIAL DAMES CO., LTD.; COTY,
INC.; FABERGÉ INC.; FRANCES DENNY, INC.; THE FULLER BRUSH
CO.; THE GEORGE W. LUFT CO., INC.; THE GILLETTE COMPANY;
A. M. HANSEN, doing business as HOUSE OF HOLLYWOOD; HARPER
METHOD, INC.; HELENA RUBINSTEIN, INC.; HELENE CURTIS IN-
DUSTRIES, INC.; HENRY/HARAN/HUTCHINGS, INC.; HERBOLD
LABORATORY, INC.; JOHN H. BRECK, INC.; KOLMAR LABORA-
TORIES, INC.; LADY LENNOX COMPANY, INC.; LEHN & FINK PROD-
UCTS CORPORATION; ARNOLD L. LEWIS, doing business as STUDIO
COSMETIC CO.; MAX FACTOR & CO.; MAYBELLINE CO.; MERLE
NORMAN COSMETICS, INC.; JACK B. NETHERCUTT, doing business as
NETHERCUTT LABORATORIES; NEUTROGENA CORP.; NUTRILITE
PRODUCTS, INC.; OLD 97 COMPANY; PRIVATE LABEL COSMETICS
CO., INC.; PURITAN COSMETICS CO.; REVLON, INC.; ROUX LABORA-
TORIES, INC.; SHULTON, INC.; and YARDLEY OF LONDON, INC.,
Petitioners,

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare, and
JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT.

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Supreme Court of the United States

OCTOBER TERM, 1966

No.

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.;
AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE
BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.;
CHESEBROUGH-POND'S INC.; CHRISTIAN DIOR PERFUMES
CORP.; CLAIROL INCORPORATED; COLONIAL DAMES CO., LTD.;
COTY, INC.; FABERGÉ INC.; FRANCES DENNY, INC.; THE
FULLER BRUSH CO.; THE GEORGE W. LUFT CO., INC.; THE
GILLETTE COMPANY; A. M. HANSEN, doing business as
HOUSE OF HOLLYWOOD; HARPER METHOD, INC.; HELENA
RUBINSTEIN, INC.; HELENE CURTIS INDUSTRIES, INC.;
HENRY/HARAN/HUTCHINGS, INC.; HERBOLD LABORATORY,
INC.; JOHN H. BRECK, INC.; KOLMAR LABORATORIES, INC.;
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PRIVATE LABEL COSMETICS CO., INC.; PURITAN COSMETICS
CO.; REVLON, INC.; ROUX LABORATORIES, INC.; SHULTON,
INC.; and YARDLEY OF LONDON, INC., *Petitioners*,

v.

JOHN W. GARDNER, Secretary of Health, Education and
Welfare, and JAMES L. GODDARD, Commissioner of Food
and Drugs, *Respondents*.

PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT.

Petitioners pray that a writ of certiorari issue to review that portion of the judgment of the United States Court of Appeals for the Second Circuit which reversed the order of the District Court as to the Fourth Count of the complaint, with instructions to grant the motion to dismiss.

Opinions Below.

The opinion of the Court of Appeals, reported at 360 F.2d 677, is in Appendix A (p. 1a, *infra*). The first opinion of the United States District Court for the Southern District of New York, reported at 235 F. Supp. 648, is in Appendix B (p. 21a). The second opinion of the District Court, as yet unreported, which is the decision from which the appeal to the Court of Appeals was taken, is in Appendix C (p. 30a).

Jurisdiction.

The judgment of the Court of Appeals is dated April 13, 1966, was entered on that date and is in Appendix D (p. 36a). The jurisdiction of this Court is invoked under 28 U. S. C. §1254(1).

Questions Presented.

I.

Whether the legality of a final agency regulation for the enforcement of a statute can be determined by the District Court under the Declaratory Judgment Act, in an action brought by a substantial number of members of the cosmetic industry, who account for approximately 90% of the sales of such industry, where:

- (a) the regulation grants the agency power and authority which it had sought from Congress in agency

sponsored legislation, namely, free access by the agency to the formulas and processes of cosmetics, but which Congress, after committee hearings, determined to withhold;

(b) the regulation has a practical impact and effect on the members of such industry, including exposure of valuable trade secrets, and such members are adversely affected and aggrieved by the agency action;

(c) the regulation is challenged as in excess of the agency's statutory authority and not in accordance with law;

(d) non-compliance with the regulation could cause the cosmetics to be banned from the market and, if thereafter sold, entail civil and criminal prosecution, seizure proceedings and harmful administrative actions; and

(e) the regulation was issued under a section of a statute which preserves judicial review by any method provided by law, and Congress had emphasized its intent that the Court have broad jurisdiction to review the agency's regulations.

II.

Whether the legality of such final agency regulation can be determined by the District Court under the Administrative Procedure Act.

The questions presented are of the same general character as those presented by the petition for a writ of certiorari to the United States Court of Appeals for the Third Circuit, granted on February 28, 1966, in *Abbott Laboratories v. Celebrezze* (No. 39)*,—a case involving other regulations of the same agency issued under the same

* The case was originally designated as No. 824, October Term, 1965 (34 LW 3289), but has been redesignated No. 39, October Term, 1966.

statute here involved. However, as shown below (pp. 17-18, *infra*), there are basic differences between the two cases which warrant the granting of this petition for a writ and hearing both cases together, rather than merely allowing this Court's decision in the *Abbott Laboratories* case perhaps to become determinative of the issues in the case at bar.

Statutes and Regulations Involved.

Statutes:

Declaratory Judgment Act, 28 U. S. C. §2201:

"§2201. Creation of remedy

"In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such."

Administrative Procedure Act, §10, 60 Stat. 243 (1946),
5 U. S. C. §1009.

"JUDICIAL REVIEW

"SEC. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

"(a) **RIGHT OF REVIEW.**—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

"(b) **FORM AND VENUE OF ACTION.**—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

"(c) **REVIEWABLE ACTS.**—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority.

"(e) **SCOPE OF REVIEW.**—So far as necessary to decision and where presented the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of any agency action. It shall (A) compel agency action unlawfully withheld or unreasonably delayed; and (B) hold unlawful and set aside agency action, find-

ings, and conclusions found to be (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (2) contrary to constitutional right, power, privilege, or immunity; (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (4) without observance of procedure required by law; (5) unsupported by substantial evidence in any case subject to the requirements of sections 7 and 8 or otherwise reviewed on the record of an agency hearing provided by statute; or (6) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations the court shall review the whole record or such portions thereof as may be cited by any party, and due account shall be taken of the rule of prejudicial error."

The foregoing statutory provisions govern the jurisdictional and procedural questions presented. The issue on the merits involves Section 201(t)(1) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 52 Stat. 1040 (1938), as amended by Section 101(c) of the Color Additive Amendments of 1960, 74 Stat. 397, 21 U. S. C. §321(t)(1), and Section 704(a) of the Act (52 Stat. 1057), as amended by Section 201 of the Drug Amendments of 1962, 76 Stat. 792, 21 U. S. C. §374(a), which are in Appendix E (p. 38a).

Regulations:

The portion of the regulation, the validity of which is challenged by the petitioners, was promulgated by the Food and Drug Administration, Department of Health, Education and Welfare ("FDA"), and is contained in Part 8, §§8.1(f), 8.28, 21 C. F. R. §§8.1(f), 8.28 (Revised as of 1966):

"§8.1 Definitions and Interpretations

"(f) * * * A substance that, when applied to the human body results in coloring, is a 'color additive,' unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives'."

"§8.28 Authority to Refuse Certification Service.

"(a) When it appears to the Commissioner that a person has:

"(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived;

he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken."

The full text of Sections 8.1(f) and 8.28 is in Appendix F (p. 41a).

Statement.

The basis for federal jurisdiction in the District Court is 28 U. S. C. §§1331(a) and 1337 (p. 3a; R. 21a).*

Petitioners are 40 companies which manufacture and distribute cosmetic products, and The Toilet Goods Association, Inc., an association of which these companies and other cosmetic companies are members (R. 14a-19a).

* References to "R. 14a" or "R. 14aa," e.g., are to the pages, respectively, of the Appendix to Appellants' Brief and the Appendix to Appellees' Brief, printed for use in the Court of Appeals. Nine copies of each Appendix have been filed with the Clerk of this Court pursuant to Rule 21(4).

Each cosmetic company is directly affected by the challenged regulation involved in this petition. To remain competitive, petitioners must constantly develop new formulae and processes for cosmetics and improve existing formulae and processes. These constitute closely guarded trade secrets of substantial value.

The challenged regulation grants FDA "free access" to such secret formulae and processes, creating a substantial danger that they may be obtained by competitors. Such danger of disclosure of secret formulae and processes would discourage research and development of new products (R. 64a, R. 4aa). But apart from such danger, petitioners have an absolute right to be free of the invasion consequent on FDA's "free access" to their secret formulae and processes, unless Congress has granted such power to FDA.

As shown below, FDA had at least twice requested Congress to grant this power as to food, drugs, cosmetics and devices as necessary for enforcement of the Act (pp. 13-16, *infra*). After extensive hearings, Congress withheld the power as to cosmetics, food, devices and non-prescription drugs,—deleting the applicable clauses from the FDA sponsored legislation,—and granted it only as to prescription drugs. By the challenged regulation, FDA simply took the power as to cosmetics. The validity of FDA's arrogation of the power of "free access" to the formulae and processes of cosmetics manufactured by the petitioners is the issue as to which petitioners seek judicial review.

Proceedings Below:

The proceedings below involved four counts of the complaint, each challenging a different provision of the same regulation as in excess of FDA's statutory authority (R. 14a, 46a, 52a, 60a). Only the Fourth Count (R. 60a),

involving FDA "free access" to secret formulae and processes, is here involved since the Court of Appeals sustained reviewability of the other three regulatory provisions, directed further proceedings in the District Court as to the merits of the first three counts, and reversed the District Court only as to the fourth (p. 20a).

However, as the District Court stated, "all four challenged regulatory provisions * * * are interrelated as elements of a common plan of governmental regulation" (p. 27a). Accordingly, a brief statement of the four aspects of the regulation will place the Fourth Count in its proper context, and show the anomaly of sanctioning judicial review of three parts of a regulation and not the fourth.

The portion of the regulation challenged by the First Count of the complaint imposes a system of premarketing clearance of finished cosmetic products by requiring that cosmetic products which impart color to the human body,—substantially all cosmetics sold in the United States,—must be pretested, listed and certified by FDA before sale (R. 14a). The portion of the regulation challenged by the Second Count requires the pretesting, listing and certification, prior to sale of the finished cosmetic product, of all its non-color ingredients (R. 46a). If the product is sold without the requisite certification or if certification is suspended, the product is *ipso facto* deemed adulterated (§§601(e), 706(a) of the Act; 21 U. S. C. §§361(e), 376(a)). Sale becomes illegal, subjecting the seller to substantial criminal and civil penalties, including multiple seizures of product (§§301(a), 302(a), 303(a), 304(a)(b) of the Act; 21 U. S. C. §§331(a), 332(a), 333(a), 334(a)(b)).

It is petitioners' position that the Act requires the pretesting, listing and certification of only the dye, pigment or other color ingredient added to the finished cosmetic prod-

net, called the "color additive," and does not require pre-testing, listing and certification of the finished cosmetic product itself or its non-color ingredients.

The portion of the regulation challenged by the Third Count changes and limits the statutory exemption for hair dyes (R. 52a).

The Fourth Count, the one involved in this petition, challenges the validity of the portion of the regulation which grants FDA inspectors "free access" to cosmetic formulae and processes, with the penalty for denial of such "free access" of suspension of certification and consequent illegality of sale (R. 60a).

Respondents moved to dismiss the complaint for alleged absence of an actual case or controversy required for justiciability, arguing that the claimed excesses of statutory authority and illegality could not be reviewed in an action under the Declaratory Judgment Act or under the Administrative Procedure Act, but could only be asserted as a defense after a specific enforcement proceeding was instituted. The District Court held a justiciable controversy existed as to all four counts, relying in part on *Abbott Laboratories v. Celebrezze*, 228 F. Supp. 855 (D. Del. 1964), which had sustained reviewability of challenged FDA regulations pertaining to labeling of drugs (pp. 21a, 23a-24a).

The Court of Appeals for the Third Circuit reversed the *Abbott Laboratories* decision, and held there was lacking an actual case or controversy required for justiciability, and that Congress intended to restrict judicial review to the administrative procedures and direct appeal to the Court of Appeals provided in the Act (352 F. 2d 286). It is from this decision, as already noted, that this Court granted certiorari (No. 39, October Term, 1966).

Respondents then renewed their motion based on such reversal of *Abbott Laboratories* (R. 100a), but this

time also urged that the Act indicated a Congressional "policy of limiting prior judicial review of administrative actions under this statute" (R. 103a), requiring pursuit of the administrative procedures prescribed in the Act, with direct appeal to the Court of Appeals (§§701(e), 706(d) of the Act; 21 U. S. C. §371(e), 376(d)). The District Court adhered to its original decision as to all four counts (p. 30a), and certified the issue for interlocutory appeal under 28 U. S. C. §1292(b) (p. 34a, R. 5a).

On April 13, 1966, the Court of Appeals affirmed as to the First, Second and Third Counts, but, as to the Fourth Count, reversed the District Court's decision as to the reviewability of FDA's assumption of power to obtain "free access" to formulae and processes for finished cosmetic products, and directed dismissal (p. 19a). The Court of Appeals held this portion of the regulation was not reviewable because it "does not of itself demand compliance at the expense of penalties" (p. 19a), but "simply warns the industry that the Commissioner may—not that he inevitably will—consider a refusal to permit such inspection a sufficient cause for suspending certification" (p. 19a). Thus, the decision as to reviewability appears to turn on the form rather than the substance of the regulation. The extent to which this distinction is in conflict with applicable decisions of this Court is shown below (pp. 22-25, *infra*).

FDA, in promulgating the regulation, followed Section 4 of the Administrative Procedure Act (the "APA"), (60 Stat. 238 (1946), 5 U. S. C. §1003), including published notice of proposed rule making (26 F. R. 679, §1003(a)), opportunity for interested persons to participate (§1003(b)) and publishing the final regulation (28 F. R. 6439, §§1002, 1003(c)). The regulation was adopted by FDA "in the avowed exercise of its rule-making power"

(*Columbia Broadcasting System, Inc. v. United States*, 316 U. S. 407, 417 (1942)); "It was final agency action" (*United States v. Storer Broadcasting Co.*, 351 U. S. 192, 198 (1956)).

The regulation expands the statutory definition of "color additive" (§201(t) (1), 21 U. S. C. §321(t) (1),—intended to mean only the dye, pigment or other color added to the product,—to include "Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body" (§8.1(f), p. 42a). It authorizes FDA to suspend certification of color additives,—defined to include such finished cosmetic products,—if denied "free access to all * * * processes, and formulae involved in the manufacture" of such finished cosmetic products* (§8.28(a)(4), p. 42a). Sale after suspension of certification makes the Act's drastic enforcement provisions immediately applicable.

The decision below that the "free access" provision may not now be reviewed because it provides that "the Commissioner may—not that he inevitably will" enforce it (p. 19a), makes an unsound distinction which ignores reality. For the entire background of the regulation makes it clear that the Commissioner intends compliance, that he "inevitably will" exercise his "free access" and that non-compliance will entail the Act's severe penalties.

Background of the "Free Access" Regulation

The original factory inspection provision authorized FDA, after "obtaining permission of the owner," to enter

* The proposed regulation published in the Federal Register, as to which interested persons were invited to present views (26 F. R. 679, Jan. 24, 1961), did not define "color additives" to include such cosmetics so that industry was not then notified that the final regulation would grant FDA "free access to all * * * processes, and formulae" of such cosmetics.

factories manufacturing food, drugs, devices and cosmetics and inspect "all pertinent equipment, finished and unfinished materials, containers, and labeling therein" (52 Stat. 1057, §704). The right to inspect processes and formulae was not granted. In 1953, following *United States v. Cardiff*, 344 U. S. 174 (1952), the Act was amended to eliminate the permission requirement (67 Stat. 477). But inspection of processes and formulae was still not granted. According to FDA's Assistant General Counsel:

"The managers of the bill expressed their opinions that it would not be a reasonable inspection to demand access to formula files * * *"

FDA subsequently sponsored the "Drug and Factory Inspection Amendments of 1962" (H. R. 11581, 87th Cong., 2d Sess.), whereby it sought access to factories "in which food, drugs, devices, or cosmetics are manufactured," and to inspect "all things therein (including * * * processes * * *)" (Appendix G, pp. 44a-45a).^{**} The accompanying "Section-by-Section Analysis" stated the purpose to "strengthen existing inspection authority" to grant FDA access to "processes" of food, drugs, devices and cosmetics (Hearings, p. 30)..

The Secretary testified that FDA inspectors "are refused access to formula files" and that (Hearings, pp. 67-8):

"H. R. 11581 would remedy this problem by granting the Food and Drug Administration authority to make complete inspection of all establishments

* Paper delivered by William W. Goodrich, Assistant General Counsel, FDA, before American Bar Association's Food, Drug & Cosmetic Law Division, Aug. 8, 1962, published in *The Business Lawyer*, Vol. XVIII, No. 1, Nov. 1962, pp. 203, 204.

** Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 87th Cong., 2d Sess., held June 19, 20, 21, 22; Aug. 20, 21, 22, 23, 1962 (the "Hearings"), p. 11.

producing foods, drugs, devices, or cosmetics. This provision would allow inspection of all . . . processes, . . ."

He further testified as to his existing authority (Hearings, p. 72):

"The Chairman: Are you authorized to look at the formula files?

"Secretary Ribicoff: We are not."

Industry opposition came not only from the cosmetic industry but from the food industry, which was most concerned at the threatened exposure of vital trade secrets.*

Congress enacted the requested "free access" to processes and formulae, but only as to factories "in which prescription drugs are manufactured" (§704 (a), 76 Stat. 792, 21 U. S. C. §374(a), Appendix E, p. 39a). It withheld the authority as to foods, non-prescription drugs, devices and cosmetics. The law, as passed October 10, 1962, dropped

* A statement by H. Thomas Austern, counsel for the National Canners Association, asserts (Hearings, p. 137):

"THREAT TO TRADE SECRETS

"Unrestricted access to FDA inspectors to files and records of food manufacturers will unnecessarily expose vital trade secrets and will seriously threaten the very existence of those companies that depend upon carefully developed recipes and processing techniques. Recipes and other trade secrets involved in the manufacture of food products are with few exceptions entrusted only to a relatively small number of personnel in each company. It cannot be questioned that trade secrets such as these are valuable property rights that benefit not only the company involved but also the consuming public.

• • • • •
 "Why the public health or safety warrants the further examination of recipes, manufacturing procedures specified, or other trade secrets is difficult to discover. As to the dangers of this power, it must be remembered that today's inspector may tomorrow be the employee of a competitor.

"Factory Inspection," from its title, and was called "Drug Amendments of 1962" (76 Stat. 780).*

To underscore the Amendments' inapplicability to cosmetics, Congress added (76 Stat. at 791, 21 U. S. C. §359):

"NONAPPLICABILITY TO COSMETICS"

"Sec. 509. This chapter, as amended by the Drug Amendments of 1962, shall not apply to any cosmetic unless such cosmetic is also a drug or device or component thereof."

FDA Counsel Goodrich stated, as to FDA access to formulae of all products:**

"We think the need is real. And we will continue with all our abilities to urge the Congress to meet the need."

Accordingly, in 1963 FDA sponsored H. R. 6788, Section 101 of which was captioned "EXTENSION OF PRESCRIPTION DRUG INSPECTION AUTHORITY TO OTHER DRUGS, FOOD, COSMETICS, AND DEVICES" (Appendix H, p. 46a). The Secretary's transmittal letter, dated May 29, 1963, referred to the "strengthened inspection authority with respect to prescription drugs" which granted access to "processes," and stated that "Similar authority is needed with respect to other products"; that FDA is hampered "when it is denied access to formulas," and that "The enclosed bill would, therefore, extend the inspection authority presently applicable only to prescription drugs to all other products

If he is, he can hardly be expected to brainwash himself of every recipe, formula, personnel record, or trade secret that he has encountered."

* These amendments and other regulations thereunder as to labeling are the ones involved in *Abbott Laboratories v. Celebrezze* (No. 39).

** Business Lawyer, Vol. XVIII, Nov. 1962, p. 207.

covered by the Food, Drug, and Cosmetic Act." (See Appendix I, pp. 48a-50a.) The requested authority was again withheld.

Subsequently, FDA, by the challenged regulation, simply took the power to obtain "free access" to all cosmetic "processes, and formulae." Its accompanying release warned that refusal of such access may cause FDA to refuse to certify the cosmetic product and "thus in effect ban it from the market" (R. 9aa).

FDA's brief below stressed its need for "free access" to cosmetic formulae, making substantially the same argument presented to Congress; namely, that such access was "plainly needful for the effective enforcement of the Act," and that the Commissioner "must have access to the plants where they [the cosmetics] are made" and to cosmetic formulae, since "There is no other way in which the Commissioner" can perform his functions*. Such assertions, coupled with its persistence in seeking the "free access" authority from Congress, makes it unlikely FDA will refrain from exercising the power taken by regulation. It is unrealistic to assume, as the court below did, that the possibility is "remote" because "No one can now say whether the Commissioner will ever make a demand for free access" (p. 19a).

FDA use of "may" rather than "will" can hardly soften the impact on the cosmetic industry of the power it illegally took or its warning it may "ban it [the product] from the market" (R. 9aa).

* Respondents' original brief in the District Court, undated, and served March 3, 1964, pp. 49, 50.

Similarly, affidavits of Oscar Garth Fitzhugh and Kenneth A. Freeman, of FDA's Bureau of Scientific Standards and Evaluations, sworn to, respectively, May 26, 1964 and May 22, 1964, submitted in support of the "free access" regulation, stated that FDA "must know the exact formula of the product" (Fitzhugh, ¶2),

Reasons for Granting the Writ.

I

The fact this Court granted certiorari in *Abbott Laboratories v. Celebrezze* (No. 39) is a significant reason for granting the writ in this case. Though both cases involve the general issue of reviewability of agency regulation by declaratory judgment and under the APA, they present entirely different facets of such issue.

Abbott Laboratories is not a case where FDA took by regulation a power Congress had withheld. Congress had imposed a specific requirement and FDA merely interpreted how such requirement could be satisfied.

The Drug Amendments of 1962 provide that a prescription drug is misbranded unless its established or generic name is "printed prominently" on the label in type half as large as any brand or proprietary name (§502 (e) (1) (B) of the Act; 21 U. S. C. §352(e) (1) (B)). Under the challenged regulation the requirement of "prominently" is satisfied only if the generic name appears each time the brand or proprietary name is used (21 C. F. R. §1.104 (g)(1)). FDA was merely interpreting the word "prominently." The Court of Appeals regarded the regulations as "interpretive regulations which represented the Commissioner's interpretation of the meaning of the Act" (*Abbott Laboratories v. Celebrezze*, 352 F. 2d 286, 289).

However, as the District Court in the case at bar stated (p. 33a):

"But the situation in this case is significantly different. Here the plaintiff contends that: . . . (3) they [the Color Additive Amendments] do not grant FDA access to industry formulae for cosmetic products and that "it is necessary that we have a full disclosure of all the ingredients in any color additive," defined to mean finished cosmetic products (Freeman, ¶4).

ucts," but that "FDA has issued regulations, purportedly under the authority of the Color Additive Amendments, which would: * * * (3) grant FDA inspectors access to cosmetic formulae. In short, the complaint contains significant allegations of administrative regulations which rather markedly depart from what preliminarily appears to be the plain legislative authority conferred by Congress. * * * this case presents a different issue of 'reviewability' or 'justiciability' than that before the court in *Abbott Laboratories*."

As the District Court further stated, this case does not involve an issue of "how the regulations are to be interpreted and applied," but "allegations of serious and significant excesses by an executive agency, through the device of final regulations, beyond the powers conferred by Congress upon the agency" (p. 33a). While the Court of Appeals considered *Abbott Laboratories* "not distinguishable on any satisfying basis" (p. 17a), it disagreed with the decision.

It is petitioners' position that, as the District Court held, the two cases present "significantly different" (p. 33a) issues of reviewability,—a fact which warrants certiorari and makes it desirable that both cases be presented to this Court at the same time.

II

With the continued expansion of administrative power and the vast increase in agency regulations, it has become increasingly important to the public, to lower courts and to the agencies affected to have an authoritative definition and clarification of when agency regulations may be reviewed by declaratory judgment and under the APA. Various courts of appeals have expressed differences as to this issue, as exemplified in the Third Circuit by *Abbott*

Laboratories, and in the Court of Appeals for the District of Columbia Circuit by *Danville Tobacco Association v. Freeman*, 351 F. 2d 832 (1965), *Helao Products Co., Inc. v. McNutt*, 137 F. 2d 681 (1943), and *American President Lines, Ltd. v. Federal Maritime Commission*, 316 F. 2d 419 (1963).

The dichotomy is manifest in the decision below where, in passing on four portions of a single regulation which "are interrelated as elements of a common plan of governmental regulation" (p. 27a), the court held three portions reviewable and the fourth not reviewable.

III

An industry is confronted with a regulation violation of which may result, in severe penalties,—the same penalties facing the drug industry under the labeling regulation in *Abbott Laboratories*.

The Congressional hearings made clear the harm to industry from disclosure of valuable trade secrets (see pp. 14-15, *supra*). Cosmetic manufacturers expend vast sums to develop new cosmetic formulae and processes. Free access to such formulae would destroy incentive for research and development work. The District Court stated that petitioners' affidavits show that granting "access to all formulae and processes will have an immediate adverse effect upon further research and development of new products" (26a). Respondents did not challenge this.

The cosmetic industry is faced with the identical dilemma as the drug industry, described in petitioners' reply brief in *Abbott Laboratories*.^{*} Here, as in *Abbott Laboratories*, if

^{*} "Petitioners should not be forced to the choice of either complying with regulations believed to be unlawful or running the risk of suffering severe sanctions. Respondents should not be permitted to hold an entire industry at hazard, arbitrarily selecting both the

the cosmetic industry cannot obtain prior review, its choice is either to comply with regulations believed to be unlawful, —and which the District Court stated “rather markedly depart from what preliminarily appears to be the plain legislative authority conferred by Congress” (33a),—or to gamble whether “may” becomes “inevitably will,” and risk having their products banned from the market.

It is insufficient protection to compel a manufacturer to await the inspector. If “free access” is granted to avoid the risk his product will be banned from the market, then he will suffer the very damage, the avoidance of which had caused Congress to deny FDA the requested authority as to foods, cosmetics, devices and non-prescription drugs, and grant it only for prescription drugs. On the other hand, if the manufacturer refuses to grant “free access” to his secret formulae and processes, then, as the FDA release warned, his products can be banned from the market. Sale will entail severe sanctions. Even if he prevails after years of litigation, the damage will have been done. There will have been a long period when his product is off the market,

companies against which these sanctions will be invoked and the drugs whose marketing will be delayed even if the regulations are ultimately held to be unlawful.” (p. 7).

• Winton B. Rankin, then FDA Assistant Commissioner for Planning, testified in his deposition taken in this case on January 22, 1965 that FDA did not have the power under the Act to inspect the formulae of cosmetic manufacturers (p. 689):

“Q. . . . Does FDA inspect or have authority to inspect the formulas of cosmetic manufacturers? A. No. This [referring to Section 704(a) of the Act] gives no authority to inspect the formulas of cosmetic manufacturers.”

Similarly, FDA Deputy Commissioner John L. Harvey, after enactment of both the Color Additive Amendments of 1960 and the Drug Amendments of 1962, referring to certain cosmetics, unequivocally stated that “under the present factory section of the law, we do not have the authority to determine the formulas used” (Business Lawyer, Vol. XVIII, No. 1, November 1962, p. 197).

with loss of profits and competitive position and injury to good will and reputation. This Court has recognized that "The harm to property and business can also be incalculable by the mere institution of proceedings." *Ewing v. Mytinger & Casselberry, Inc.*, 339 U. S. 594, 599 (1950).

A person unable to obtain prior judicial review can thus be whipsawed into surrender of his rights and compliance with illegal regulations because the consequences of being right are as disastrous as being wrong.

The Declaratory Judgment Act was particularly designed to cover this very situation, and to assure that persons adversely affected by agency regulations claimed to be illegal need not wait for the axe to fall before obtaining judicial review. The Senate Report on the Act states:

"The [declaratory judgment] procedure has been especially useful in avoiding the necessity, now so often present, of having to act at one's peril or to act on one's own interpretation of his rights, or abandon one's rights because of a fear of incurring damages" (S. Rep. No. 1005, 73d Cong., 2d Sess., p. 2 (1934)).

Borchard has noted that the declaratory judgment procedure has special application to agency regulations, stating that "Possibly in no branch of litigation is the declaration more useful than in the relations between the citizen and the administration" ("Challenging 'Penal' Statutes by Declaratory Action," 52 Yale L. J. 445 (1943)).

IV

Each reason advanced below to justify the decision that the "free access" regulation is not ripe for review is in conflict with applicable decisions of this Court.

The Court below found unripeness because (pp. 19a-20a):

(a) The challenged regulation "does not of itself demand compliance at the expense of penalties"; "It simply warns the industry that the Commissioner may—not that he inevitably will"—consider denial of free access cause to suspend certification and ban the product from the market;

(b) "No one can now say whether the Commissioner will ever make a demand for free access" to processes or formulae of cosmetics or "whether any manufacturer will ever decline this"; and

(c) It "is not a sufficient basis for declaratory relief" that the risk of "the possible consequences of refusal may induce manufacturers to be more compliant".

Each such reason is in conflict with *Columbia Broadcasting System, Inc. v. United States*, 316 U. S. 407 (1942); *Frozen Food Express v. United States*, 351 U. S. 40 (1956); and *United States v. Storer Broadcasting Co.*, 351 U. S. 192 (1956).

The Columbia Broadcasting System Case:

There the regulations were not issued as "final". Accordingly, they nowhere demanded compliance but, as in the case of the "free access" regulation at bar, required action by the agency. This Court, however, held that the regulations were subject to prior judicial review even though they "are not directed to appellant and do not in terms compel action by it or impose penalties upon it because of its action or failure to act" (316 U. S. at 422). It further held that reviewability was unaffected by the

fact that the regulations were "not directed to any particular person or corporation," or that "their promulgation did not operate of their own force * * *" (p. 417). "Such regulations have the force of law before their sanctions are invoked as well as after" (p. 418).

The argument that the regulations were not reviewable on issuance because described by the agency as "nothing more than the expression of the general policy we will follow" (p. 411, fn. 1) was rejected as "addressed to the form rather than the substance" (p. 419). Similarly, the holding below that the "free access" regulation is not ripe for review because it merely warns that "the Commissioner may—not that he inevitably will" enforce the regulation, is also "addressed to the form rather than the substance."

This Court also held that an administrative order is reviewable where there is risk of penalty, and "it does not cease to be so merely because it is not certain whether the Commission will institute proceedings to enforce the penalty * * *" (pp. 417-8):

"It is common experience that men conform their conduct to regulations by governmental authority so as to avoid the unpleasant legal consequences which failure to conform entails" (p. 418);

"the expected conformity to them causes injury cognizable by a court of equity" (p. 419).

Reviewability is also unaffected by the fact that the regulation is not couched as a direct grant of access authority but indirectly accomplishes the same result, through the penalty of banning the product from the market, with all the consequences attendant on illegal sale. For, as this Court stated, "it is the substance of what the [agency] has purported to do and has done which is decisive" (p. 416).

The decision below that the regulation is not now ripe for review, and the reasons advanced by the court for such decision, are in direct conflict with the *Columbia Broadcasting System* case.

The Frozen Food Express Case:

The regulation there involved likewise did not "demand compliance" (p. 19a) and Mr. Justice Harlan dissented because it "nowhere commands" compliance (351 U. S. at 45). In fact, that case did not involve a final regulation, but the agency had merely "announced its definition" of a statutory term,—which caused the lower court to hold the order not reviewable (128 F. Supp. 374, 377). This Court, however, sustained reviewability because the order "warns" the industry that violation would involve "the risk of incurring criminal penalties," so that it is not "abstract, theoretical, or academic," but "touches vital interests" of the industry there involved (p. 44),—language which shows the error in the decision below that this "free access" regulation is not reviewable because it "simply warns the industry" (p. 19a).

The Storer Broadcasting Case:

The petitioner Storer, as the dissent noted, did not even allege "present injury of any kind," the challenged regulations "impose no duty," and there was no "possibility of criminal penalties" (351 U. S. at 209, 212, 212 fn. 3). Yet, this Court found "ripeness" for review, since "The process of rulemaking was complete" (pp. 197, 198), and "standing to seek review," since "The Rules now operate to control the business affairs of Storer" (pp. 197, 199).

Similarly, FDA's process of rulemaking was complete with promulgation of its final regulations, and those regula-

tions "now operate to control the business affairs" of the entire cosmetic industry.

This Court,—reaffirming the *Columbia Broadcasting System* case,—again held that regulations are reviewable even though they "did not command [the party seeking review] to do or refrain from doing anything" (p. 198), and "do not in terms compel action by it or impose penalties upon it because of its action or failure to act" (p. 199),—statements totally in conflict with the decision below that there cannot be review because the challenged regulation "does not of itself demand compliance at the expense of penalties" (19a).

In failing to apply to the Fourth Count the principles of the *Columbia Broadcasting System*, *Frozen Food Express* and *Storer Broadcasting* cases, the Court below enunciated an entirely new principle. This would enable a federal agency by regulation to take power withheld by Congress, to warn industry of the drastic consequences of resisting exercise of such power, and, by merely providing that the power "may" be exercised without asserting it "inevitably will," to prevent prior judicial review through declaratory judgment or under the APA. The court below has provided federal agencies with a ready device for taking power withheld by Congress and preventing effective judicial review.

V

The court below decided an important question of federal law which should be settled by this Court when it denied reviewability by declaratory judgment and under the APA because the challenged regulation authorizes one whose certification has been suspended, with his product

banned from the market, to request a hearing with review by the court of appeals under §§706(d) and 701(f) of the Act, 21 U. S. C. §376d, 371(f) (p. 19a).*

However, such a hearing is limited to "the factual basis for the suspension" (§8.28(b), p. 43a). The factual basis for the suspension would be self-evident, namely, refusal to permit "free access" to secret cosmetic formulae and processes. The hearing would not even present the issue whether FDA had exceeded its statutory authority when it promulgated a regulation granting such "free access." Furthermore, as the District Court stated, "it is scarcely to be thought that judicial review limited to the traditional and narrow scope of whether or not the Commissioner's findings are supported by adequate evidence can supplant the other and broader form of remedy or review available under the Declaratory Judgment Act" (p. 34a).

The decision below that the ostensible remedy for review of the "free access" regulation in an administrative hearing precludes review by declaratory judgment is contrary to the expressed intention of Congress. As the District Court stated, "subsection (f)(6) of Section 701 of the Act underscores the Congressional intention" that the administrative remedy, with direct appeal to the court of appeals, "shall be in addition to and not in substitution for any other remedies provided by law" (34a). The House

* The issue whether existence of such an administrative "remedy" precludes declaratory judgment or a remedy under the APA is also presented in *Abbott Laboratories*, but, as shown above, in connection with a different type of regulation (pp. 17-18, *infra*). The Solicitor General, in opposing certiorari, agreed "there may be substance to petitioners' contention" as to ripeness and a justiciable issue being presented, but took the position that the Act's provisions for administrative hearing and review "demonstrate Congress' intention to limit the instances in which the agency may be forced to defend its issued regulations prior to its enforcement of them" (p. 4).

Report on the original Act,—which fully considered the procedure for administrative review of regulations, with direct appeal to the court of appeals, referred to the Act's saving clause (§701(f)(6), 52 Stat. 1056, 21 USC §371(f)(6)), and stated:

“There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.

“The special type of review above outlined, where the proceedings are instituted by the individual or business organization affected, will permit an early determination of the validity of the Secretary's action with respect to any proposal for a regulation, amendment, or repeal, and make for prompt certainty as to legal rights.” H. R. Rep. No. 2139, 75th Cong., 3d Sess., p. 11 (1938).

The House Report further emphasized that the court can give the fullest possible review and hold a regulation invalid “if for any other reason it was not in accordance with the law” (p. 12):

“The committee amendment is silent as to any limitations on the court in holding invalid the order of the Secretary. The court is thus left free to exercise its right of review to the full extent that it may constitutionally do so.”

Furthermore, in limiting petitioners to an administrative hearing with review by the Court of Appeals, the decision below is in conflict with *Stark v. Wickard*, 321 U. S. 288 (1944), where this Court held that agency power “is circumscribed by the authority granted”; that courts are entrusted with the protection of “justiciable individual

rights against administrative action fairly beyond the granted powers"; and that "The responsibility of determining the limits of statutory grants of authority in such instances is a judicial function" (pp. 309-10). Accordingly, this Court sustained judicial reviewability by injunction "in the ordinary courts in the absence of some exclusive alternative remedy" (p. 290). See also, *Heikkila v. Barber*, 345 U. S. 229, 232 (1953).

Since this issue is also before this Court in *Abbott Laboratories*, but in the context of a different type of regulation, it can only aid decision of this important question of federal law if the case at bar is simultaneously considered.

VI

(1) The Court below also stated as a reason for not reviewing the "free access" regulation, that "it is impossible to see what declaration a court could properly make" (20a),—a point not raised below in briefs or oral argument. The answer is simple. The declaration would be that the provisions of §§8.1(f) and 8.28(a)(4) of the regulations granting free access to cosmetic formulae and processes are not authorized by the Act and are in excess of statutory authority.⁶ In effect, these provisions would be deemed deleted from the regulation.

This presents no greater problem than Congress had when FDA sponsored proposed bills granting access to formulae and processes for all products covered by the Act, and Congress deleted the portion applicable to cosmetics, food, non-prescription drugs and devices, and limited such access to prescription drugs. (See pp. 14-15, *supra*):

At the trial on the merits, the District Court will have ample opportunity, with the benefit of briefs and oral

argument, to explore the kind of declaration which would be proper. It should be no ground for refusing to hear the merits of an action for a declaratory judgment because, without the issue even having been suggested, an appellate court has difficulty at the threshold, and without the merits before it, to see what declaration the District Court could properly make.

(2) It may also be noted that the statement below that "Congress' failure to empower the agency to compel an inspection of processes or formulae" does not show Congressional intent that FDA should not have this power "when the public cannot properly be protected otherwise," (p. 20a) is in conflict with applicable decisions of this Court. This is not a case of mere omission by Congress affirmatively to give FDA access to cosmetic formulae and processes, and where perhaps a possible Congressional intent that FDA should have an implied power can somewhere be found. This is a case where FDA repeatedly asserted it lacked this power and needed it in order properly to protect the public, and requested Congress to grant it, and Congress, after hearings, expressly determined to withhold it as to cosmetics, while granting it as to prescription drugs. Under such circumstances Congress' failure to grant certain power to an agency shows an unequivocal intent that the agency not have the power. *Flora v. United States*, 362 U. S. 145, 162-3 (1960); *Boire v. Greyhound Corp.*, 376 U. S. 473, 479 (1964); *Continental Casualty Co. v. United States*, 314 U. S. 527, 533 (1942); *Carey v. Donohue*, 240 U. S. 430, 436-7 (1916).

In *Federal Communications Commission v. American Broadcasting Co., Inc.*, 347 U. S. 284, 296 (1954), this Court held that an agency had "overstepped the boundaries" and "exceeded its rule-making power" when, "without success,

it urged Congress to amend the law" and then sought "to accomplish the same result through agency regulations."

VII

The petition presents an important question as to reviewability of federal regulations under the Administrative Procedure Act which should be settled by this Court.

The Court of Appeals, having found jurisdiction under 28 U. S. C. §§1331 and 1337, and having sustained reviewability of the portions of the regulation involved in the first three counts of the complaint, did "not reach the question whether §10 of the Administrative Procedure Act, 5 U. S. C. §1009, constitutes an affirmative grant of jurisdiction with respect to the review of federal administrative action" (3a, fn. 1). However, since it held that the Fourth Count as to "free access" did not present "sufficient basis for declaratory relief" (20a), it would have to consider whether such portion of the regulation could be reviewed under the APA. But it simply ignored the APA.

However, the action as to all counts is clearly authorized by Section 10 of the APA, 5 U. S. C. §1009,—an act "to be given a 'hospitable' interpretation". *Shaughnessy v. Pedreiro*, 349 U. S. 48, 51 (1955).

The "free access" regulation is clearly an agency "Rule" and "Agency action" within the meaning of Section 2(c) and (g), 5 U. S. C. §1001(c) and (g). Manufacturers facing compulsory disclosure of valuable trade secrets, at the risk of having their products banned from the market, with sale entailing severe criminal and civil penalties, are clearly persons "adversely affected or aggrieved" by the agency action, as provided in Section 10(a), 5 U. S. C. §1009(a).

As shown above (p. 26), the "remedy" of administrative hearing is inadequate, as limited to "the factual basis for the suspension" (21 CFR §8.28(b)). Accordingly, clearly the "free access" regulation is an act reviewable under Section 10(c), 5 U. S. C. §1009(c), as "final agency action for which there is no other adequate remedy in any court."

Finally, as to the scope of review, Section 10(e), 5 U. S. C. §1009(e), authorizes the court to "(B) hold unlawful and set aside agency action . . . (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right".

As stated in *Rusk v. Cort*, 369 U. S. 367, 372 (1962), "On their face the provisions of these statutes appear clearly to permit action such as was brought here . . ." Both *Frozen Food Express* (351 U. S. at 42) and *Storer Broadcasting* (351 U. S. at 195) were under the APA, though this Court did not discuss its application.

Since the APA was intended to broaden the scope of judicial review of agency action, this petition presents the opportunity to amplify the application and scope of review of federal regulations under the APA,—an issue of substantial significance to federal agencies and industry.

VIII

Finally, the District Court enunciated a principle applicable to review of agency regulations which the Court of Appeals rejected, but which is so administratively sound that it should be approved by this Court.

The four counts, involving separate portions of a single regulation, are, as the District Court stated, "interrelated as elements of a common plan of governmental regulation". Accordingly, it recognized it was desirable "to

examine all four challenged regulatory provisions together within the context of a single plenary proceeding" (27a).

The interrelationship of the four provisions as "a common plan of governmental regulation" is manifest from the fact that the four provisions were all contained in FDA sponsored legislation which Congress refused to enact.*

There is no remaining issue,—unless respondents should seek a writ as to the first three counts,**—that the portion of the regulation involved in such counts are proper subjects for judicial review by declaratory judgment. It makes no sense, and is administratively undesirable, to have the provisions involved in these three counts now adjudicated by declaratory judgment, but, as to the provision involved in the Fourth Count, to compel industry to await some indefinite future date when validity might or might not be determined, with a sword of Damocles meanwhile hanging. Nor does it make sense to postpone adjudication of the legality of this important regulatory provision until a multitude of individual enforcement proceedings may ensue from denial of free access to cosmetic formulae and processes, with consequent banning of the products from the market.

* See, e.g., H. R. 11581, H. R. 11582, 87th Cong., 2d Sess., May 3, 1962, Hearings, pp. 2-19; H. R. 6788, 88th Cong., 1st Sess., June 4, 1963.

** On July 6, 1966, the Solicitor General applied for a 30-day extension of time for filing a petition for a writ of certiorari with respect to the decision below on the first three counts. The extension was granted by Mr. Justice Stewart, by order signed July 7, 1966.

Conclusion.

The petition for a writ of certiorari should be granted.

Respectfully submitted,

July 11, 1966

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APPENDIX A.

Opinion of the United States Court of Appeals, For the Second Circuit.

(Filed April 13, 1966.)

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.;
AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE
BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.;
CHESEBROUGH-POND'S INC.; CHRISTIAN DIOR PERFUMES
CORP.; CLAIROL INCORPORATED; COLONIAL DAMES CO.,
LTD.; COTY, INC.; FABERGE INC.; FRANCES DENNY, INC.;
THE FULLER BRUSH CO.; THE GEORGE W. LUFT CO.,
INC.; THE GILLETTE COMPANY; A. M. HANSEN, doing
business as HOUSE OF HOLLYWOOD; HARPER METHOD,
INC.; HELENA RUBINSTEIN, INC.; HELENE CURTIS INDUS-
TRIES, INC.; HENRY/HARAN/HUTCHINGS, INC.; HERBOLD
LABORATORY, INC.; JOHN H. BRECK, INC.; KOLMAR LABO-
RATORIES, INC.; LADY LENNOX COMPANY, INC.; LEHN &
FINK PRODUCTS CORPORATION; ARNOLD L. LEWIS, doing
business as STUDIO COSMETIC CO.; MAX FACTOR & CO.;
MAYBELLINE CO.; MERLE NORMAN COSMETICS, INC.; JACK
B. NETHERCUTT, doing business as NETHERCUTT LABORA-
TORIES; NEUTROGENA CORP.; NUTRILITE PRODUCTS, INC.;
OLD 97 COMPANY; PRIVATE LABEL COSMETICS CO., INC.;
PURITAN COSMETICS CO.; REVLON, INC.; ROUX LABORA-
TORIES, INC.; SHULTON, INC.; and YARDLEY OF LONDON,
INC.,

Plaintiffs-Appellees,

v.

JOHN W. GARDNER, Secretary of Health, Education and
Welfare, and JAMES L. GODDARD, Commissioner of Food
and Drugs,

Defendants-Appellants.

Before:

WATERMAN, MOORE and FRIENDLY,

Circuit Judges.

Appendix A.

Appeal by the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs from an order of the District Court for the Southern District of New York, Harold R. Tyler, Jr., *Judge*, denying their motion to dismiss or grant summary judgment in an action for a declaration of invalidity of four Food and Drug Administration regulations relating to color additives. . Affirmed as to Counts 1, 2 and 3; reversed as to Count 4.

ARTHUR S. OLICK (Robert M. Morgenthau, United States Attorney for the Southern District of New York; James G. Greilsheimer, Assistant United States Attorney, of Counsel), *for Defendants-Appellants*.

EDWARD J. ROSS (Breed, Abbott & Morgan, New York, N. Y.; Stephen R. Lang, of Counsel), *for Plaintiffs-Appellees*.

FRIENDLY, Circuit Judge:

In July 1960, Congress added to the Federal Food, Drug, and Cosmetic Act a number of new provisions known as the Color Additive Amendments, 74 Stat. 397, 21 U. S. C. §§321-376. These were intended

“to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerance, under which such additives may be safely used.” H. R. Rep. No. 1761, 86th Cong., 2d Sess., 1960 U. S. Code Cong. & Ad. News 2887.

The Commissioner of Food and Drugs, to whom the Secretary of Health, Education and Welfare has delegated the Department's functions under the Act, 22 F. R. 1051 (1957),

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25 F. R. 8625 (1960), held rule-making proceedings conforming to §4 of the Administrative Procedure Act, 5 U. S. C. §1003, and issued Color Additive Regulations, 21 C. F. R. Part 8, effective, with certain exceptions, on June 22, 1963.

The following November the Toilet Goods Association, a trade organization of cosmetic manufacturers whose members allegedly represent 90% of annual United States sales, and forty manufacturers and distributors of cosmetics brought this action against the Secretary and the Commissioner in the District Court for the Southern District of New York for a declaratory judgment that four provisions of the Regulations exceeded the authority conferred by the statute. Jurisdiction was properly predicated on 28 U. S. C. §§1331 and 1337. See *Smith v. Kansas City Title & Trust Co.*, 255 U. S. 180 (1921).¹ The defendants moved to dismiss or to strike certain portions of the complaint on various grounds, among others that the case was inappropriate for declaratory relief and that the action was an unconsented suit against the sovereign; plaintiffs cross-moved for summary judgment. In November 1964 Judge Tyler denied both motions in an opinion, 235 F. Supp. 648, relying in part on *Abbott Labs. v. Celebrezze*, 228 F. Sup. 855 (D. Del. 1964), where the court had granted a declaratory judgment invalidating labeling regulations under the same statute. A year later, when the case was nearly ready for trial, the Secretary and the Commissioner renewed their

¹ We thus do not reach the question whether §10 of the Administrative Procedure Act, 5 U. S. C. §1009, constitutes an affirmative grant of jurisdiction with respect to the review of federal administrative action, as the Supreme Court apparently assumed in *Rusk v. Cort*, 369 U. S. 367, 371-72 (1962) and we recently did in *Cappadora v. Celebrezze*, — F. 2d — (2 Cir. 1966). But see *Ove Gustavsson Contracting Co. v. Floete*, 278 F. 2d 912 (2 Cir.), cert. denied, 364 U. S. 894 (1960). Since 28 U. S. C. §§1336-40 do not require a jurisdictional amount, this question arises only in cases such as social security, passport and citizenship matters; where none of these sections is applicable and the jurisdictional amount required by §1331 is not met.

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motion to dismiss on the two grounds stated, arguing that a different conclusion on "the issue of justiciability" was called for by the Third Circuit's reversal of the *Abbott Laboratories* decision, 352 F. 2d 286 (1965),² and the District of Columbia Circuit's recent holding that declaratory relief was not available to challenge certain regulations adopted under the Tobacco Inspection Act, 7 U. S. C. §714(b), *Danville Tobacco Ass'n v. Freeman*, 351 F. 2d 832 (D. C. Cir. 1965). Judge Tyler adhered to his determination but, at the defendants' request, made the necessary certification for an application to prosecute an interlocutory appeal under 28 U. S. C. §1292(b); permission to appeal was granted by a panel of this court.

I.

The first two counts of the complaint charge that the Regulations exceed the authority conferred by the statute in treating finished cosmetic products and all diluents—unpigmented materials with which colors are mixed—as "color additives" subject to various requirements for testing and administrative certification. The basic section of the Color Additive Amendments is §706 of the Act, 21 U. S. C. §376, which provides that a "color additive" shall be deemed unsafe unless it meets two conditions:³ The additive must be covered by a "regulation," issued by the Secretary on a finding of suitability, which lists it for use either generally or under prescribed conditions; and it must either come from a batch certified for such use by the Secretary under appropriate regulations or have been exempted from the certification requirement.

The term "color additive," on which the controversy turns, is defined in §201(t)(1), as a material which

² Subsequent to the argument of this appeal, certiorari was granted, 34 U. S. L. Week 3294 (March 1, 1966) (No. 824).

³ This is subject to an exception, not here important, for color additives covered by an exemption for investigational use by qualified experts, 21 U. S. C. §§376(a)(2) and (f).

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(A) is a dye, pigment, or other substance made by a process of synthesis... or otherwise derived... from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto.

21 U. S. C. §321(t)(1)

The Regulations of the Food and Drug Administration (FDA) interpret the statutory definition of color additive as including "all diluents" and state further that

A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." Reg. §8.1(f).

The term "diluent" is defined as:

any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

Reg. §8.1(m)

The manufacturers admit that the coloring ingredient in a cosmetic is a "color additive" fully subject to both

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listing and certification requirements of §706, and that a "diluent," in what they insist is the accepted definition of an inert substance used to dilute dyes and pigments, is subject to the Secretary's power to certify additives "with safe diluents or without diluents," §706(c). They complain, however, that the Regulations' comprehensive definition of "color additive" goes beyond the reach of the statute in imposing both listing and certification requirements on finished products—like lipstick, nail polish, etc.—and non-color ingredients that were never intended to be subject to premarketing clearance, and on traditional diluents that were meant to be subject only to certification as components of dyes and pigments.

The third count of the complaint relates to provisions in the Regulations which attempt to subject hair dye products to premarketing clearance in what is alleged to be violation of the exemption recognized in the statute. The Act as passed in 1938, in defining those cosmetics that were deemed to be adulterated, contained in §601(a) an explicit exemption for hair dyes:

This provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing.

52 Stat. 1054

The exemption was carried forward in §601(e) which declared that a cosmetic should be deemed adulterated "If it is not a hair dye and it bears or contains a coal-tar color other than one" from a certified batch. When Congress revised the statute in the 1960 Amendments, it left §601(a) as it was but modified §601(e) to read "If it is not a hair

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dye and it is, or it bears or contains, a color additive which is unsafe" within the meaning of §706.

The Regulations recognized the statutory exemption where proper labeling called for use of the patch test but, armed with an expansive definition of "color additive" in §8.1(f) which would on its face seem to include in a preparation for use on the hair any coloring ingredient as well as the finished product, proceeded to limit the exemption as follows:

The "hair dye" exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious substance in the "hair dye" is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.

Reg. §8(u)

The manufacturers claim that the Regulations go beyond the statute in several ways: Whereas the 1938 Act literally exempted from premarketing clearance any coal-tar hair dye complying with the statutory condition of notice and the amendments did not purport to effect any change, the Regulations grant exemption only if the color additive in the hair dye substance is one whose irritating qualities would be detected by a patch test; and, contrary to the

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longstanding interpretation—in effect by regulation when the amendments were adopted⁴—which applied the exemption in its full scope to dual-purpose hair products like shampoos, rinses and tints with a coal-tar coloring component, the Regulations seem to limit the exemption to the coloring ingredient itself.

Count 4 of the complaint attacks a section of the Regulations, §8.28(a)(4), which states that when it appears to the Commissioner that a person has refused to permit duly authorized employees of the FDA “free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived,” he may suspend certification service to such person until adequate corrective action is taken. The first sentence of §704(a) of the Act, applicable to all goods, drugs, devices, or cosmetics subject thereto, authorizes the Secretary to inspect any “factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labelling therein”; the second sentence, dealing only with places where prescription drugs are manufactured, processed or held, provides for inspection extending “to all things therein (including records, files, papers, processes, controls, and facilities).” The manufacturers say the challenged regulation illegally extends to cosmetics the broadened inspection authorized only for prescription drugs, and improperly subjects trade secrets to exposure.

The expanded definition of “color additives,” the narrowing of the hair dye exemption, and the allegedly compelled disclosure of secret formulae and processes impose, the manufacturers claim, burdens not contemplated by the statute and threaten immediate and irreparable injury. Even though coloring ingredients have been properly pre-

⁴ Reg. §1.200 apparently defined the term “coal-tar hair dye” in the §601(a) exemption to include “all articles containing any coal-tar color.” This definition of hair dyes was deleted by the Commissioner as superseded by §8.1(u) of the Color Additive Regulations, 28 F. R. 10638 (1963).

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tested, listed and certified in compliance with the statutory clearance scheme, the regulations require filing a separate listing application for each finished product, traditional diluent and non-color ingredient, including those formerly exempted under the hair dye provision; each application must be accompanied by a \$2600 filing fee, Reg. §8.50(c), and supported by extensive scientific tests establishing suitability for intended use, Reg. §8.4(c). Even after listing, every ingredient and finished product must come from a certified batch unless the Secretary has granted an exemption; a minimum fee of \$100 is charged for each certification, Reg. §8.51(a). An affidavit by one manufacturer claimed that the listing of its finished products alone for the issuance of regulations would entail filing fees of \$7,000,000 and testing costs of nearly \$42,000,000, and that certification fees for a single year would amount to \$750,000.⁵ Beyond such out-of-pocket costs, increased by substantial additional expenses for record-keeping, compliance with the challenged regulations, by requiring significant changes in established business practices and curtailing distribution of new products, allegedly would cause major and costly disruption of the cosmetic industry. Moreover, the disclosure of formulae and processes necessary to meet the new listing requirements and to avoid loss of certification for refusing inspection allegedly would result in misappropriation of trade secrets and discourage research and development of improved cosmetic products.

Failure to comply with the challenged regulations could have serious consequences if they are valid. Under §601 of the Act, a cosmetic other than a hair dye is deemed adulterated if "it is, or it bears or contains, a color additive which is unsafe" within the meaning of §706(a). Projection of any adulterated article into the stream of interstate com-

⁵ Very likely these figures are exaggerated since they take no account either of the FDA's power to require information on diluents as a condition of approving coloring ingredients and granting certification or of the likelihood of exemption from certification.

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merce and refusal to allow inspection required by §704 are prohibited acts under the statute, and are subject to injunction and entail criminal liability, §§301-303; and any adulterated article may be seized under §304. The manufacturers say that, apart from all else, the publicity incident to criminal or civil proceedings against them for failure to comply with the Regulations would be seriously detrimental in a highly competitive industry which spends millions in cultivating public good will and is dependent on consumer confidence in the integrity of its products.

The Secretary and the Commissioner respond that the fears as to the dilemma posed by the Regulations are exaggerated. They insist that the Regulations merely expound the manner in which they intend to construe the amendments, that nothing has yet been done to apply the provisions of which plaintiffs complain, and that ample opportunity to test the Regulations in concrete fact situations is afforded by the path for review spelled out in the statute. If the manufacturers will only comply with the listing and certification requirements, the FDA's application of the statute will, under §706(d), be subject to the general administrative provisions on hearings and review in §701. Since the review authorized in §706(d) is directed at decisions approving or disapproving listing and certification and §§701(e) and (f) are limited to review of other specifically enumerated agency determinations, the contention is not that the statutory provisions afford a direct path to review of the general regulations on listing requirements; it is rather that they furnish an indirect but nevertheless sufficient one which the manufacturers ought to have taken. The proper course, defendants say, is for a manufacturer to petition for the listing of diluents and finished cosmetic products as color additives, while protesting against the need for doing so and conforming with the detailed requirements for filing information only to the extent he believes proper under the statute; such a petition could be accompanied by a request for exemption from batch certification,

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again with appropriate protest and non-compliance with the requirement of factual data to support the application. Either the FDA would retreat from applying its announced interpretation of the statute and grant the petition and the request for exemption, or it would deny them in which event the road to a court of appeals would be open under §§701(e) and (f).

II.

The serious questions⁶ are whether direct challenge of the Regulations by suit in a district court is impliedly barred by the availability of review of listing and certification denials in a court of appeals, and whether the controversy is appropriate for judicial determination prior to application of the Regulations in a particular factual situation.

We are not persuaded that by providing a procedure for review of certain administrative decisions under the Food and Drug Act in the courts of appeals, Congress meant to foreclose relief with respect to other agency action under the Administrative Procedure Act §10, 5 U. S. C. §1009, or the Declaratory Judgment Act, 28 U. S. C. §2201, in a case where this would otherwise be appropriate. The agency determinations specifically reviewable under §701(e) relate to such technical subjects as chemical properties of particular products and the formulation and application of safety standards for protecting public health; Congress naturally did not wish courts to consider such

⁶ We need not discuss in the text the surprising contention that an action for a declaration that federal regulatory officers have acted in excess of their authority constitutes an unconsented suit against the United States. The contrary is clearly established by *Philadelphia Co. v. Stimson*, 223 U. S. 605, 619-20 (1912), see *Stark v. Wickard*, 321 U. S. 288, 290 (1944), and indeed follows inevitably from *Ex parte Young*, 209 U. S. 123 (1908); law officers of the Government ought not to take the time of busy judges or of opposing parties by advancing an argument so plainly foreclosed by Supreme Court decisions.

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matters without the benefit of the agency's views after an evidentiary hearing before it. Section 701, however, also contemplated other less specialized administrative action by authorizing, in subsection (a), the making of regulations for the efficient enforcement of the statute, and it expressly declared in subsection (f) that the provision for review of certain orders in the courts of appeals was "in addition to and not in substitution for any other remedies provided by law." 21 U. S. C. §371(f)(6). The section as a whole does not indicate to us any congressional intent either to insulate administrative action not covered by subsection (e) from challenge as in excess of statutory authority, see *Stark v. Wickard*, 321 U. S. 288, 308-11 (1944); cf. *Cappadora v. Celebrezze*, 356 F. 2d 1, 5 (2 Cir. 1966), or to postpone immediate challenge to such action where awaiting the issuance of adjudicative orders subject to statutory review would provide less effective relief.⁷ Insofar as *Abbott Labs. v. Celebrezze*, 352 F. 2d 286, 289 (3 Cir. 1965), cert. granted, intimates otherwise, we are unwilling to follow it.

The question whether a plaintiff may obtain judicial relief in cases like this has been variously phrased as

⁷ The legislative history of the 1938 Act suggests that Congress had no intention of limiting review of other action by adopting a special procedure for the enumerated determinations. The House Report, referring to the savings clause in §701(f)(6), stated:

There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.

H. R. Rep. No. 2139, 75th Cong., 3d Sess., p. 11 (April 14, 1938).

The accompanying minority report, in endorsing the Secretary's challenge to the new review provisions as jeopardizing enforcement of the statute, indicated that the special procedure was understood to be an additional protection for industry and not an exclusive method of review of all actions for the benefit of the agency. H. R. Rep. 2139, Pt. 2 (April 21, 1938).

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whether he has "standing" to challenge the administrative action as a person "suffering legal wrong" or "aggrieved" within the meaning of §10 of the APA, whether the dispute is an "actual controversy" within the Declaratory Judgment Act, or whether it is sufficiently "ripe" for resolution by the courts. See Jaffe, *Judicial Control of Administrative Action* 395-98 (1965). In fact, the critical issue is apt to be less a matter of standing or of actual controversy than of the advisability of reviewing an administrative rule prior to its application in a specific factual situation. The current healthy trend toward implementing agency policy by rule-making cuts both ways with respect to declaratory relief—increasing the need for this sort of assistance on the part of those subjected to such rules, see *Columbia Broadcasting Sys., Inc. v. United States*, 316 U. S. 407, 421 (1942), but also creating a danger that, unless the courts are circumspect, administration may be improperly halted, at least temporarily, before it has gotten the slightest start.⁸ The problem is not to be solved, as the parties suggest, by applying some readily procurable litmus paper which will determine whether a controversy is "justiciable"; what is required, as in the case of challenge to the constitutionality of a statute, is a reasoned evaluation of "both the appropriateness of the issues for decision by courts and the hardship of denying judicial relief." *Joint Anti-Fascist Refugee Comm. v. McGrath*, 341 U. S. 123, 156 (1951) (Frankfurter, J., concurring); see Jaffe, *supra*, at 396, 423.

The appropriateness of passing judgment on the validity of an administrative regulation prior to its application to

⁸ The danger of unwarranted postponement of the effectiveness of agency action is augmented by the fact that a suit for declaratory relief must be brought in a district court, twice removed from the supreme tribunal, whereas adjudicative orders are generally reviewable either in courts of appeals or in specially constituted district courts from which appeal lies directly to the Supreme Court. Yet here too there is another side; a district court may be in a better position than a court of appeals to carry out fact finding, as Congress recognized in the Hobbs Act, 5 U. S. C. §1037(b).

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particular facts depends on such factors as how far the rule represents the definitive position of the agency and the extent to which the challenge raises a clearcut legal issue susceptible of judicial solution without reference to fact variables arising in its implementation. Cf. *Northeast Airlines, Inc. v. CAB*, 345 F. 2d 662, 664 (1 Cir. 1965). Review might be considered premature where an agency rule had not received substantially as full consideration in its formulation as it would have in subsequent application, or where future experience would be likely to result in significant modifications as to its precision or scope. Judicial determination might also be deemed inappropriate where the controversy over the rule did not present a legal issue that a court was qualified to resolve without reference to factual determinations more effectively made by the agency familiar with day to day administration. See Jaffe, *supra*, at 406. In this case, however, the Regulations under attack were issued after a full hearing with notice and by their terms represent the definitive agency position on the reach of the statutory requirements for listing and certification of cosmetics, see *Columbia Broadcasting Sys., Inc. v. United States*, *supra*, 316 U. S. at 422; *United States v. Storer Broadcasting Co.*, 351 U. S. 192, 198 (1956); to the extent that they purport to apply premarketing requirements to broad categories like finished products and non-coloring ingredients and define the hair-dye exemption, they appear, *prima facie*, to be susceptible of reasoned comparison with the statutory mandate without inquiry into factual issues that ought to be first ventilated before the agency. Indeed, it is manifest that if the manufacturers adhere to their legal position, *pro forma* individual applications to the FDA for listing and certification would produce a record no more, and very likely less, illuminating than what the district court will develop at trial of this action in which the great bulk of the industry is represented and will be bound. The mere fact that the procedure which the defendants suggest would bring the issue

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directly to a court of appeals without prior resort to a district court, while entitled to some weight, is not controlling. As indicated earlier, the statutory procedure for review of individual determinations in the courts of appeals was not intended as a means for challenging FDA rule-making of the usual sort; as shown by the authorities discussed below, the mere fact that pursuit of that course could produce a decision on legal issues similar to that here sought does not make its use mandatory.

With respect to the other relevant consideration, the degree of hardship warranting declaratory relief, although some older precedents suggest broadly that an administrative ruling is not reviewable until and unless it imposes an obligation or subjects the plaintiff to some civil or criminal liability, see, e.g., *United States v. Los Angeles & Salt Lake R.R.*, 273 U. S. 299, 309-10 (1927); *Shannahan v. United States*, 303 U. S. 596, 599 (1938), there has been a growing recognition that the timeliness of review depends on a broader concept of the substantiality of present or immediate harm. See 3 Davis, *Administrative Law Treatise* §2107 (1958). In *Columbia Broadcasting Sys., Inc. v. United States*, 316 U. S. 407, 417-21 (1942), the Supreme Court declared that though a particular rule does not of itself deny a license or directly impose sanctions, it may nevertheless be reviewable if it establishes a general standard of conduct which by its very promulgation demands conformity and poses, for the plaintiff or others with whom he must deal, the alternatives of compliance or severe penalties of forfeiture or disruption of business operations. In *Frozen Food Express v. United States*, 351 U. S. 40, 43-44 (1956), the Court recognized that an agency order generally announcing the scope of administrative regulation was subject to immediate frontal attack, although opportunities for later challenge were sure to come from a cease and desist order by the ICC, see *Eastern Texas Motor Lines v. Frozen Food Express*, 351 U. S. 49 (1956),

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or suit for an injunction by the agency or competitors.⁹ And in *United States v. Storer Broadcasting Co.*, 351 U. S. 192, 199-200 (1956), declaratory rules setting limits on the number of licenses to be granted for broadcasting stations under common ownership were held to be immediately reviewable because they operated "to control the business affairs" of the plaintiff and made it impossible to "coherently plan its present or future operations" so long as their validity remained undetermined; direct challenge to the regulations was permitted even though review might have been obtained by provoking an adverse administrative order, see 351 U. S. at 208 (dissenting opinion).¹⁰ See also *Flemming v. Florida Citrus Exch.*, 358 U. S. 153, 168 (1958).

We see little profit in debating the point, much discussed by the parties, whether the Regulations are "interpretative" or "legislative." Although that issue would have to be faced if the FDA had failed to comply with the rule-

⁹ If it be said that the carrier was subject to liability for criminal penalties even before a cease and desist order or an injunction, the same is true here.

¹⁰ In fact the FCC dismissed the plaintiff's application for an additional station on the basis of the new rules the very day they were adopted, 351 U. S. at 197, but review of the particular decision was not sought.

We recognize that in *Storer* review of the rule was in the Court of Appeals for the District of Columbia, the same tribunal to which *Storer* would have gone for review of the denial of an application; but the dissenters thought the rationale of the majority would support a suit for declaratory relief in a district court after the 60-day limitation for seeking review by the Court of Appeals had expired, 351 U. S. at 210 (dissenting opinion of Harlan, J.). A more important differentiating consideration may be that awaiting denial of a future application may not have afforded a broadcaster who had reached the ceiling so full an opportunity for challenge as might appear at first blush; if the application was a competitive one for a new license, the FCC might predicate denial on other grounds, and to negotiate a transfer of an existing license in the teeth of the multiple-ownership rules would be of dubious business practicality. However, this ground for distinguishing *Storer* would not apply to *Frozen Food Express*.

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making procedures of §4 of the APA because of a claim on its part that the Regulations were merely "interpretative," the interpretative character of a regulation does not necessarily make it unripe for review; we perceive no reason why a rule whereby an agency subjects to regulation activities contended to be immune should be exempt from immediate review because it purports to interpret a statute although it would not be if made in the exercise, contended to be illegal, of a substantive rule-making power. See *Frozen Food Express v. United States*, *supra*; Jaffe, Judicial Control of Administrative Action 405-07 (1965); and 1 Davis, Administrative Law Treatise §5.03 (1965 Pocket Part), criticizing on this ground *American President Lines, Ltd. v. FMC*, 316 F. 2d 419 (D. C. Cir. 1963), on which defendants rely. Neither do we think anything is to be gained by an attempt at comprehensive review of the decisions; the many cases in this area are not truly reconcilable and the law has been moving in the direction of greater freedom of review, see Jaffe, *supra*, at 412-17 (which, *inter alia*, criticizes another decision relied on by defendant, *Helco Prods. Co. v. McNutt*, 137 F. 2d 681 (D. C. Cir. 1943)), and 3 Davis, Administrative Law Treatise §§21.06-21.08 (1958). We limit ourselves to the two recent Court of Appeals decisions which defendants most strongly urge upon us.

Danville Tobacco Ass'n v. Freeman, 351 F. 2d 832 (D. C. Cir. 1965), was a rather weak case for declaratory relief. The plaintiffs there were neither threatened with penalties nor, like those in *Frozen Food* and here, faced with the need of applying for licenses to permit continuation of an established business; moreover, there was no showing that the challenged regulation was in fact preventing expansion of their operations, since they had filed no applications and petitions by other applicants had been denied on grounds other than those attacked. Agreeing with the defendants that *Abbott Labs. v. Celebrezze*, 352 F. 2d 286 (3 Cir. 1965), cert. granted, is not distinguishable on any satisfying basis,

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we must confess, with all respect, our inability to understand why the plaintiffs there should be required to violate the challenged FDA regulation in order to raise the same legal issue as to which the district court had granted declaratory relief. Insofar as the *Abbott* decision rested on a negative implication from the limited review provisions of the Food and Drug Act, we have already noted our inability to agree.

III.

In applying the general considerations thus developed to the precise issues here presented, we must bear in mind that this appeal is not from a declaratory judgment but from the denial of a motion to dismiss a complaint seeking one. The issue on such an appeal is not whether the grant of a declaratory judgment was in fact appropriate but whether it so clearly would not be that dismissal *in limine* was required.

As regards the counts of the complaint challenging the inclusion of finished products and color additives and the alleged restrictions of the hair-dye exemption, the appeal must fail. These Regulations appear to have an immediate impact on the industry, posing the unacceptable alternatives of complying or of incurring possible forfeitures and criminal liability, and calling into question long standing practices of premarketing testing and clearance. The issues framed by the counts of the complaint addressed to these Regulations appear sufficiently suitable for immediate judicial resolution and the threatened harm sufficiently great, that the district court properly declined to dismiss them. If the court should find that the issues are not susceptible of resolution without detailed factual evidence that ought to be first sifted by the agency, or that measures being taken by the FDA for the listing and exemption from certification of approved diluents have so reduced the hardship on the plaintiffs as to make declaratory relief inap-

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appropriate, it need not proceed to judgment. But, so far as we can now see, the sooner the industry's claims as to the coverage of the Act in these respects are determined, the better for everybody. As said in Jaffe, *Judicial Review of Administrative Action* 404 (1965), "The public has an interest in early implementation of policy; the regulated person has a legitimate interest whether to plan or not to plan his operation." Moreover, the party disappointed by court decision may wish to take the case to Congress.

The fourth count of the complaint, relating to agency inspection of formulae and processes, stands differently. Here the challenged regulation, §8.28(a)(4), does not of itself demand compliance at the expense of penalties. A manufacturer who refuses access to his trade secrets is not threatened with criminal liability or seizure; the regulation does not suggest that such refusal will be deemed a "prohibited act" under the statute, as it would be in the case of prescription drugs. It simply warns the industry that the Commissioner may—not that he inevitably will—consider a refusal to permit such inspection a sufficient cause for suspending certification. Moreover, the next paragraph, §8.28(b), says that upon receipt of notice of suspension, the person so notified may request a hearing upon the factual basis therefor. If after such hearing the Commissioner should adhere to his refusal to certify, review by a court of appeals would seem available under §§706(d) and 701(f); if not, an action could be brought in the district court.

In this instance the possibility of unlawful injury to the plaintiffs is, on its face, too remote for declaratory relief. No one can now say whether the Commissioner will ever make a demand for free access to color additive processes or formulae, whether any manufacturer will ever decline this, what the Commissioner would do if so refused, and what result a hearing would have. The fact that the Commissioner's proclamation of the possible consequences of refusal may induce manufacturers to be more compliant

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than if he had kept silent until an episode calling for action arose is not a sufficient basis for declaratory relief. Moreover, it is impossible to see what declaration a court could properly make. No one could reasonably assert that circumstances warranting suspension of certification if a manufacturer refused to give the FDA information concerning processes or formulae could never arise; Congress' failure to empower the agency to compel an inspection of processes or formulae is not a mandate to grant certificates when the public cannot properly be protected otherwise. Review of this Regulation should be on a case by case basis and with a factual record to assist in determining whether access to secret processes and formulae is necessary and appropriate to performance of the task of effective premarketing clearance in a particular instance—at least in the absence of experience showing consistent abusive tactics.

The judgment with respect to Count 4 is reversed with instructions to grant the motion to dismiss; the judgment with respect to Counts 1, 2 and 3 is affirmed, with further proceedings to be promptly taken in the district court in accordance with this opinion.

APPENDIX B.

**First Opinion of the United States District Court
For the Southern District of New York.**

Civil Action 63 Civ. 3349

(Filed November 16, 1964)

THE TOILET GOODS ASSOCIATION, INC., *et al.*,
Plaintiffs,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education
and Welfare, and George P. Larrick, Commissioner of
Food and Drugs, Defendants.

TYLER, District Judge.

Forty individuals and companies manufacturing, distributing, and selling cosmetics in interstate commerce and an association of cosmetic manufacturers here seek a declaratory judgment [28 U.S.C. §2201] as to the validity of certain provisions of regulations promulgated by the Commissioner of the Food and Drug Administration (FDA). These regulations were issued pursuant to the 1960 Color Additives Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-381.¹ More specifically, plaintiffs contend that the challenged regulations exceed the authority vested in the FDA by the statute, as amended, and pray that the court declare the regulations null and void and enjoin their enforcement.

Essentially, the 1960 Amendments expand the Act's provisions for the pretesting of coal tar colors to require the pretesting of all color additives, irrespective of their derivation. To this end, the term "color additive" is

¹ The Amendments were enacted on July 12, 1960.

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defined as "a dye, pigment, or other substance" which, "when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable * * * of imparting color thereto." 21 U. S. C. §321(t)(1). The Amendments further state that color additives shall be deemed "unsafe" within the meaning of the Act unless they conform to regulations for the listing of additives and for "the certification, with safe diluents or without diluents, of batches of color additives." 21 U. S. C. §376.

To implement these Amendments, the Commissioner of the FDA issued the Color Additives Regulations, dated June 13, 1963.² 26 F. R. 6439, 21 C. F. R. §§8.1-8.6003. Those provisions of the regulations here challenged as in excess of the statutory authority on which they purport to be based are:

(a) provisions of Section 8.1(f) which, it is claimed, may have the effect of defining a color additive as including finished cosmetic products, and consequently, of requiring the pretesting of finished products;

(b) provisions of Sections 8.1(f) and (m) which define color additives as including all diluents and which, plaintiffs claim, may require the pretesting, listing and certification of all ingredients of cosmetics containing a color additive mixture;

(c) provisions of Sections 8.1(f) and (u) which are claimed to make nugatory the statutory exemption for hair dyes, 21 U. S. C. §361(a) and (e); and

(d) provisions of Section 8.28(a)(4) which plaintiffs contend is an unwarranted grant of access by FDA investigators to all processes and formulae involved in the manufacture of cosmetics.

² Actually, 21 U. S. C. §371(a) vests in the Secretary of the Department of Health, Education and Welfare the authority to promulgate Food & Drug Act regulations. Defendants' memoranda explain that the responsibility for their actual promulgation was delegated to the Commissioner.

Appendix B.

Defendants have moved for an order dismissing the complaint, and, alternatively, for an order "striking certain portions of the complaint."³

I.

Defendants' principal contention on their motion to dismiss is that the complaint fails to state a case of actual controversy, as required by the Declaratory Judgment Act, 28 U. S. C. §2201, particularly because of the absence of any threatened or attempted enforcement of the regulations.

Although the Declaratory Judgment Act was never intended or construed to grant the federal courts license to render advisory opinions, threatened enforcement of a statute or administrative regulation is not a *sine qua non* for its review under the Act. See Borchard, *Declaratory Judgments* (2d ed., pp. 365-6). In *Columbia Broadcasting System, Inc. v. United States*, 316 U. S. 407, 417-418, 62 S. Ct. 1194, 1200, 86 L. Ed. 1563 (1942), FCC regulations provided that radio stations would have their licenses revoked if they entered into contracts with networks containing certain prohibited clauses. The court held the regulations to be reviewable because of their serious impact upon the radio network's ability to conduct its business and stated that, "If an administrative order has that effect it is reviewable and it does not cease to be so merely because it is not certain whether the Commission will institute proceedings to enforce the penalty incurred under its regulations for non-compliance."

Recently, in *Abbott Laboratories v. Celebrezze*, 228 F. Supp. 855 (D. Del. 1964), where drug manufacturers challenged FDA labeling regulations, Chief Judge Wright held, at page 861:

"Plaintiffs may have judicial review of interpretive regulations upon their promulgation without

³ Defendants, however, have not specified which portions they wish stricken.

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awaiting some ultimate enforcement. *Frozen Food Express v. United States*, 351 U. S. 40, 76 S. Ct. 569, 100 L. Ed. 910 (1956); *Federal Trade Commission v. Nash-Finch Company*, 110 U. S. App. D. C. 5, 288 F. 2d 407. They need not await an action which would only make the threat of harm more pressing."

Thus, while the threat of enforcement is often present in cases where the courts have taken jurisdiction and rendered a declaratory judgment on the validity of a challenged regulation or statute, the existence of such a threat merely serves as some evidence indicating the presence of an actual controversy and that the plaintiff stands to suffer "real, immediate and incalculable" harm. See concurring opinion of Mr. Justice Douglas, *Joint Anti-Fascist Refugee Committee v. McGrath*, 341 U. S. 123, 175, 71 S. Ct. 624, 95 L. Ed. 817 (1951).

In *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U. S. 270, 273, 61 S. Ct. 510, 512, 85 L. Ed. 826 (1940), the Supreme Court said that, "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

More specifically, as to the reviewability of administrative rulings, Chief Justice Stone said in *Columbia Broadcasting System, Inc. v. United States*, *supra*, 316 U. S. at page 425, 62 S. Ct. at page 1204:

"The ultimate test of reviewability is not to be found in an overrefined technique, but in the need of the review to protect from the irreparable injury threatened in the exceptional case by administrative rulings which attach legal consequences to action taken in advance of other hearings and adjudications that may follow, the results of which the regulations purport to control."

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This being the test, I find it difficult and indeed inappropriate, at least under the circumstances here presented, to resolve the issue of reviewability upon the technical distinction, pressed by defendants, between legislative and interpretive regulations. Parenthetically, I should add that I read no federal authority to precisely support the defendants' argument that the regulations here involved are "interpretive" as opposed to "legislative" and thus do not "approach a degree of finality such as would warrant access to the Courts". (See page 59 *et seq.* of the government's principal brief.)⁴

In any event, for reasons to be discussed hereinafter, I conclude that in a substantial and practical business sense plaintiffs are threatened with irreparable injury by the obviously intended consequences of the challenged regulations, and that to resort to later piecemeal resolution of the controversy in the context of individual enforcement proceedings would be costly and inefficient, not only for the plaintiffs but as well for the public as represented by the defendants.

The regulations force manufacturers to choose between complying with them, at a cost that may prove to be prohibitive for some of the plaintiffs, or ignoring them at the risk of incurring the statutory penalties should the regulations later be held valid. And, as Chief Judge Wright recently observed in the *Abbott Laboratories* case, *supra*, 228 F. Supp. at 862: "The declaratory judgment procedure is specifically suited for the determination of controversies where the plaintiffs must either comply with a contested regulation or continue their present course of conduct at their peril."

⁴ In fairness to defendants, however, it must be said that some commentators and courts have discussed this distinction in theoretical terms. See Davis, *Administrative Rules—Interpretative, Legislative and Retroactive*, and cases therein cited. 57 Yale L. J. 919, 928-29 (1948).

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An affidavit submitted on behalf of one of the plaintiffs asserts that the cost of compliance to this plaintiff alone will be over \$50,000,000. While this amount is immediately suspect,⁵ there can be little doubt but that the added records-keeping and laboratory testing costs in themselves will be extremely burdensome for all of the plaintiffs.

Aside from such measurable out-of-pocket costs of compliance, it is not difficult to perceive that the impact of the regulations on plaintiffs' present methods of doing business will be substantial and will give rise almost certainly to potentially greater expenses. That the latter are "hidden expenses" in the sense that they are presently incalculable does not diminish their significance. For example, in the area of research alone, plaintiffs' affidavits show that the provisions of the regulations dealing with listing and with access to all formulae and processes will have an immediate adverse effect upon further research and development of new products. The situation here, incidentally, contrasts sharply with the facts of *Helco Products Co. v. McNutt*, 78 U. S. App. D. C. 71, 137 F. 2d 681, 149 A. L. R. 345 (1943), where the plaintiff sought a declaratory judgment on the validity of a simple advisory opinion of the FDA elicited in response to the plaintiff's inquiry whether or not its proposed business venture would violate the Food and Drug Act. Rather, we are dealing with a case that more closely parallels *Wallace v. Currin*, 95 F. 2d 856 (4th Cir. 1938), aff'd., 306 U. S. 1, 59 S. Ct. 379, 83 L. Ed. 441 (1939). The court in that case held that the plaintiffs, tobacco warehousemen, could challenge the 1955 Tobacco Inspection Act in a declaratory judgment suit because of the Act's substantial interference with their businesses, notwithstanding the fact that the cost of compliance for each warehouseman would only be \$25 per marketing season.

⁵ The affiant apparently confused §8.50(c) of the regulations, which requires a deposit of \$2,600 for each listing application, with §8.50(j), which establishes a fee of \$250 "for services in listing a diluent" for use in color additive mixtures.

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Having established that a justiciable controversy exists, there are at least two compelling reasons for assuming jurisdiction and determining in this action the validity of the challenged regulations.

First, since a concern for consumer safety is ostensibly the principal motive underlying promulgation of the Color Additives Regulations, there is a strong public interest in an early determination of their validity. Four years have already elapsed since Congress enacted the statutory provisions which the regulations seek to implement. Any further delay in determining whether or not the cosmetic industry need comply with the regulations will only serve to further frustrate Congress' purpose of providing the consuming public with protection against potentially harmful color additives.

● Second, this action provides an opportunity to examine all four challenged regulatory provisions together within the context of a single plenary proceeding. Since these four provisions are interrelated as elements of a common plan of governmental regulation, there is a distinct advantage in reviewing them together. Moreover, since the regulations raise complicated and technical issues which will require expert testimony to resolve—undoubtedly from many of the same witnesses—there is a practical advantage for the litigants as well as for the court in having this testimony brought forth in a single action rather than in four or more separate suits or enforcement proceedings.

II.

Since I conclude that there is a justiciable controversy presented and further that it would be improvident to decline jurisdiction on discretionary grounds, this would dispose of the dismissal motion were it not for the fact that defendants raise two further arguments for dismissal of the entire action and two other arguments for dismissal as to certain of the plaintiffs. All four issues so raised must be resolved against defendants, at least at this stage of the proceedings:

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(1) This is not an unconsented suit against the United States. Keeping in mind the distinction drawn in *Larson v. Domestic & Foreign Commerce Corp.*, 337 U. S. 682, 69 S. Ct. 1457, 93 L. Ed. 1628 (1949), the thrust of the claim here is not that the Commissioner wrongly exercised his delegated powers—which would be a claim against the sovereign—but that he acted in excess of his statutory authority and therefore outside the scope of his delegated powers. And, as the Supreme Court said in *Larson*, at 689, 69 S. Ct. at 1461, “where the officer’s powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions.” See *Abbott Laboratories v. Celebrezze*, *supra*; *Philadelphia Company v. Stimson*, 223 U. S. 605, 32 S. Ct. 340, 56 L. Ed. 570 (1912); *Federal Trade Commission v. Nash-Finch Company*, 110 U. S. App. D. C. 5, 288 F. 2d 407 (1961).

(2) The Attorney General is not an indispensable party to this action. This was the conclusion in the *Abbott Laboratories* case where the court said 228 F. Supp. at page 862: “The decree sought here does not operate against the Attorney General except in a secondary fashion. He will not be forced to do anything no matter how the court decides.”

(3) The Toilet Goods Association does have standing to sue. The members of the Association account for more than 90% of the annual sales of cosmetics in the United States. They are individually harmed and the Association, as a proper representative of the interests of its members, can challenge the regulations in that capacity. *National Motor Freight Traffic Association v. United States*, 372 U. S. 246, 83 S. Ct. 688, 9 L. Ed. 2d 709 (1963); *Abbott Laboratories v. Celebrezze*, *supra*.

(4) Venue, predicated upon 28 U. S. C. §1391(c), is proper as to each of the individually named plaintiffs. Although not all the Circuits agree, this Circuit has consistently held that 28 U. S. C. §1391(c) applies to plaintiff

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and defendant corporations alike. *Freiday v. Cowdin*, 83 F. Supp. 516 (S. D. N. Y. 1949); *Southern Paperboard Corporation v. United States*, 127 F. Supp. 649 (S. D. N. Y. 1955); *Wear-Ever Aluminum Inc. v. Sipos*, 184 F. Supp. 364 (S. D. N. Y. 1960).

Accordingly, defendants' motion to dismiss is denied in all respects.

III.

Since the papers already submitted by the parties raise substantive issues outside this court's ordinary sphere of competence, it would be unwise to make a determination on the merits at this stage without the aid of "live", expert testimony.

To be sure, the essential questions presented in this action are ones of statutory interpretation; whatever competence the court and counsel may have in this area generally, however, can only be enhanced by a particular understanding, to be obtained with expert assistance, of the technical problems involved. Additionally, since professionally qualified representatives of both plaintiffs and defendants were present during the hearings and debates which preceded the passage of the 1960 Color Additives Amendments, it would be helpful to hear their testimony relative to legislative intent, which, presumably, they had an important role in shaping and assisting.

Plaintiffs' motion for summary judgment, therefore is denied.

IV.

Inasmuch as defendants have not specified what they wish to have stricken from the complaint, their motion to strike is denied.

Settle order accordingly.

APPENDIX C.

**Second Opinion of the United States District Court
for the Southern District of New York.**

Civil Action 63 Civ. 3349

(Filed December 13, 1965)

The TOILET GOODS ASSOCIATION, INC., *et al.*,
Plaintiffs,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education
and Welfare, and GEORGE P. LARRICK, Commissioner of
Food and Drugs, Defendants.

TYLER, D. J.

Defendants (hereinafter collectively referred to as "FDA"), with the permission of this court, have made a renewed motion to dismiss the complaint and for summary judgment pursuant to F. R. C. P. 56 and 28 U. S. C. 2201 on the grounds that the complaint fails to set forth a justiciable controversy and that this is an unconsented suit against the United States. In the alternative, defendants have moved for an order pursuant to the provisions of 28 U. S. C. 1292(b) certifying the aforesaid issues for an interlocutory appeal.

By way of background, the principal impetus for this renewed motion stems from recent opinions filed by the United States Courts of Appeals for the Third Circuit in *Abbott Laboratories v. Celebrezze, et al.*, 352 F. 2d 286, decided November 1, 1965, and for the District of Columbia in *The Danville Tobacco Association et al. v. Freeman*, 351 F. 2d 832, decided September 30, 1965. Both decisions, in general terms, were rulings that the district courts should

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have dismissed complaints for failure to state justiciable controversies where complainants were ostensibly challenging the meaning and validity of agency regulations. Thus, FDA here asserts that the facts of the present case are substantially analogous to those in *Abbott and Danville Tobacco*, and that, therefore, the decision of this court filed on November 17, 1964 and determining, among other things, that the present case presents a justiciable controversy in a context not involving an unconsented suit against the United States, should be reconsidered and overturned.

The parties amply briefed the issues upon this renewed motion, and oral argument were heard on December 6, 1965. On December 8, 1965, this court filed an order denying the renewed motion of FDA for dismissal but certifying the questions presented for an interlocutory appeal. This memorandum is designed to sketch the principal reasons for this court's refusal to disturb its original determination filed approximately one year ago.

No useful purpose can be served here in replowing the same ground covered in the opinion of this court reported at 235 F. Supp. 648. Essentially, I do not agree with FDA's arguments that *Abbott and Danville Tobacco* present facts and circumstances apposite to the case at bar.¹

As already indicated in the earlier opinion of this court, FDA in the last analysis has consistently bottomed all of its arguments upon the technical proposition that the regulations here under attack are "interpretive" as opposed to "legislative".² This cornerstone contention of FDA, it seems to me, has several deficiencies. Preliminarily, it smacks of hypertechinicality; in the words of Chief Justice Stone, "the ultimate test of reviewability is not to be found

¹ Indeed, *Danville Tobacco* seems to me so obviously inapposite as to warrant no detailed discussion whatsoever. I suspect that FDA in part would agree because its papers and oral argument were principally keyed to *Abbott*, with little or no detailed discussion of *Danville Tobacco*.

² See discussion in 57 Yale L. J. 919, 928-9 (1948).

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in an over-refined technique...". *Columbia Broadcasting System, Inc. v. United States*, 316 U. S. 407, 425 (1942). More significant, this court has already found upon the allegations of the complaint in this case that FDA has promulgated final regulations pursuant to the Color Additives Amendments of 1960 enacted by Congress as part of the Food, Drug and Cosmetics Act (74 Stat. 397, Public Law 86-618, 86th Cong., 2d Session, 21 U. S. C. 321 (+) and 376) (hereinafter the "Act"); that there is raised by the parties a substantial issue as to whether or not four of these final regulations significantly exceed the legislative mandate of the 1960 Amendments; and that irreparable harm would attach to plaintiffs unless these issues are resolved in this declaratory judgment action prior to piecemeal administrative litigation upon individual license applications. It is in the light of these findings that I reach my opinion that *Abbott*, and, of course, *Danville Tobacco*, are distinguishable from this case.

Granting *arguendo* that *Abbott Laboratories* is generally more similar to the present controversy, it must be emphasized that there the applicable statutory provision³ merely required that with respect to prescription drugs, the established or generic drug name be printed "prominently" on the label in type half as large as any brand or proprietary name. Presumably, this "prominently" requirement could be satisfied in a number of ways such as by means of a special label in large type-face, or by printing the generic name in bold red letters and the like. In its pertinent regulations, FDA in effect provided that the generic name must be shown "prominently" not only on labels but "each time" the trade name is used for any purpose, whether it be advertising, labelling or whatever. Perhaps understandably under these circumstances, the Court of Appeals ruled that the issue presented was one of interpretation of the regulations in question and, as such, not cognizable by the district court.

³ Section 502(e)(1)(B) of the Act.

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But the situation in this case is significantly different. Here the plaintiff contends that: (1) the 1960 Color Additive Amendments require merely pretesting, listing and certification for dyes, pigments and other color ingredients; (2) they do not change the statutory exemption for hair dyes; and (3) they do not grant FDA access to industry formulae for cosmetic products. But plaintiffs also allege that FDA has issued regulations, purportedly under the authority of the Color Additive Amendments, which would: (1) require pretesting, listing and certification for finished cosmetic products, including hair dyes, and, as well, for the non-color ingredients of finished cosmetics; (2) change and limit the statutory exemption for hair dyes; and (3) grant FDA inspectors access to cosmetic formulae. In short, the complaint contains significant allegations of administrative regulations which rather markedly depart from what preliminarily appears to be the plain legislative authority conferred by Congress in the 1960 Color Additives Amendments.⁴ Thus it is that in my opinion this case presents a different issue of "reviewability" or "justiciability" than that before the court in *Abbott Laboratories*.⁵ Upon the complaint allegations, this is not necessarily a case where, as FDA is prone to argue, the parties are simply bickering as to how the regulations are to be interpreted and applied. Rather, on the face of the pleadings, this is a case involving allegations of serious and significant excesses by an executive agency, through the device of final regulations, beyond the powers conferred by Congress upon the agency in the 1960 Amendments. Whether or not these claims are true presents, in my view, a justiciable controversy which is ripe for determination by a district court under the Declaratory Judgment Act.

⁴ For other possible distinguishing factors, see discussion of this court at 235 F. Supp. at pages 651-2.

⁵ Moreover, even if it be said that this case is not distinguishable from *Abbott*, then I would disagree with the reasoning and ultimate result to date of the latter case.

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In reaching the latter conclusion, I am not unaware of another argument of FDA which, though not novel, takes on special focus by virtue of certain discussion of the Court of Appeals in *Abbott Laboratories*. FDA urges as a principal argument against reviewability here that Congress has provided another and more efficacious remedy for aggrieved industry members. In substance, this is the remedy of judicial review by a Court of Appeals from individual orders of the FDA upon applications for licenses for cosmetics, all as set forth in subsection (f)(1-5) of Section 701 of the Act. Apparently, FDA obtains comfort from certain statements concerning this statutory method of review by the Court of Appeals at pages 8 and 9 of its slip opinion in *Abbott Laboratories*. But, as I see it, such is cold comfort indeed in view of the fact that the Court of Appeals in *Abbott Laboratories* at the threshold had determined that they were concerned with an interpretative as opposed to "legislative" regulations such as are alleged in the case at bar. Moreover, subsection (f)(6) of Section 701 of the Act underscores the Congressional intention that the special review of license proceedings by the Courts of Appeals "shall be in addition to and not in substitution for any other remedies provided by law". Finally, it is scarcely to be thought that judicial review limited to the traditional and narrow scope of whether or not the Commissioner's findings are supported by adequate evidence can supplant the other and broader form of remedy or review available under the Declaratory Judgment Act.

A brief, final paragraph may be in order respecting that part of this court's December 8, 1965 order certifying the questions pursuant to 28 U. S. C. 1292(b). Aside and apart from the circumstance that plaintiffs have agreed to the FDA's request for certification, it is clear from a review of the general case law in this field that, notwithstanding my firmly held views on the issues here of justiciability and whether or not this is an unconsented suit against the sovereign, there is ample room for difference of opinion.

Appendix C.

Further to bespeak the obvious, a different view than mine would quickly terminate this litigation, which, though only commenced last year due to doubtless necessary delays in the regulation making process, involves subject matters passed upon by the Congress five years ago. Even if the reviewing court were to agree that this court has properly taken jurisdiction, it must be borne in mind that this case was ready to proceed to trial on December 6, 1965, the day when this renewed motion was argued—i.e. in the event of an unsuccessful interlocutory appeal, this case presumably can be resolved on the merits without undue additional delay.

December 10, 1965.

/s/ H. R. TYLER, JR.
U. S. D. J.

APPENDIX D**Judgment of the Court of Appeals****UNITED STATES COURT OF APPEALS****FOR THE SECOND CIRCUIT.**

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Courthouse in the City of New York, on the thirteenth day of April one thousand nine hundred and sixty-six.

Present:

HON. STERRY R. WATERMAN,

HON. LEONARD P. MOORE,

HON. HENRY J. FRIENDLY,

Circuit Judges.

THE TOILET GOODS ASSOCIATION, INC., *et al.*,
Plaintiffs-Appellees,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education
and Welfare, and GEORGE P. LARRICK, Commissioner of
Food and Drugs,

Defendants-Appellants.

Appeal from the United States District Court for the
Southern District of New York.

This cause came on to be heard on the transcript of
record from the United States District Court for the South-
ern District of New York, and was argued by counsel.

Appendix D.

ON CONSIDERATION WHEREOF, it is now hereby ordered, adjudged, and decreed that the order of said District Court be and it hereby is affirmed as to the First, Second and Third Counts of the complaint.

It is further ordered that the order of said District Court be and it hereby is reversed as to the Fourth Count of the complaint with instructions to grant the motion to dismiss in accordance with the opinion of this court.

A. DANIEL FUSARO
Clerk

APPENDIX E

Federal Food, Drug, and Cosmetic Act, as Amended

Section 201(t), 52 Stat. 1040 (1938), as amended by Section 101(c) of the Color Additive Amendments of 1960, 74 Stat. 397 (1960), 21 U.S.C. §321(t):

"CHAPTER II—DEFINITIONS

"SEC. 201. For the purposes of this Act—

“(t) (1) The term ‘color additive’ means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

“(2) The term ‘color’ includes black, white, and intermediate grays.

“(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of

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produce of the soil and thereby affecting its color, whether before or after harvest."

Section 704(a), 52 Stat. 1057 (1938), as amended by Section 201 of the Drug Amendments of 1962, 76 Stat. 792 (1962), 21 U.S.C. §374(a):

"FACTORY INSPECTION

"SEC. 704 [374]. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing

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on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of this Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

APPENDIX F**Regulations of the Food and Drug Administration,
21 CFR Part 8****"Subpart A—Definitions and Procedural and Interpretative Regulations****"§ 8.1. Definitions and interpretations.**

"(f) A 'color additive' is any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting a color thereto. This includes all diluents. Substances capable of imparting a color to a container for foods, drugs, or cosmetics are not color additives unless the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the color being transmitted to the contents of the package or any part thereof. Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as 'color additives'; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a 'color additive.' Food ingredients as authorized by a definition and standard of identity prescribed by regulations pursuant to section 401 of the act are 'color additives,' where the ingredients are specifically designated in the definitions and standards of identity as permitted for use for coloring purposes. An ingredient of an animal feed whose intended function is to impart, through the biological

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processes of the animal, a color to the meat, milk, or eggs of the animal is a color additive and is not exempt from the requirements of the statute. This definition shall apply whether or not such ingredient has nutritive or other functions in addition to the property of imparting color. A substance that, when applied to the human body results in coloring, is a 'color additive,' unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives.' An ingested drug the intended function of which is to impart color to the human body is a 'color additive.' For the purposes of this part, the term 'color' includes black, white, and intermediate grays, but substances including migrants from packaging materials which do not contribute any color apparent to the naked eye are not 'color additives.' "

§ 8.28 Authority to refuse certification service.

"(a) When it appears to the Commissioner that a person has:

(1) Obtained, or attempted to obtain, a certificate through fraud or misrepresentation of a material fact.

(2) Falsified the records required to be kept by §8.26; or

(3) Failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the correctness of such records, as required by §8.26; or

(4) Refuse to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived;

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he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

“(b) Upon receipt of the notice of suspension of service, the person so notified may request a hearing upon the factual basis for the suspension. The procedure at the hearing shall conform as nearly as possible to the procedure described in §§130.14-130.26 of this chapter.”

(5776)

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APPENDIX G.

The Proposed Factory Inspection Provisions of H. R. 11581

"[H.R. 11581, 87th Cong., 2d sess.]

"A BILL To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the Act; and to amend related laws

"Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act, divided into titles and sections according to the following table of contents, may be cited as the 'Drugs and Factory Inspection Amendment of 1962'.

"TITLE II—CLARIFICATION AND STRENGTHENING OF FACTORY INSPECTION AUTHORITY

FACTORY INSPECTION

"SEC. 201. (a) The first sentence of subsection (a) of section 704 of the Federal Food, Drug, and Cosmetic Act is amended to read as follows: 'For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any consulting laboratory, or to enter any vehicle being used to transport or hold

Appendix G.

such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, consulting laboratory, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, and all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether articles which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violations or potential violations of this Act'."

APPENDIX H

The Proposed Factory Inspection Provisions of H. R. 6788

"88th Congress 1st Session

H. R. 6788

"A BILL To protect the public health by amending the Federal Food, Drug and Cosmetic Act to extend and clarify existing inspection and investigative powers, require a pre-marketing showing of the safety of cosmetics, assure the safety, efficacy, and reliability of therapeutic, diagnostic, and prosthetic devices, improve the statutory coordination between that Act and the biological-drug provisions of the Public Health Service Act, provide for cautionary labeling of articles where needed to prevent accidental injury, and for other purposes.

"Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act, divided into titles and sections according to the following table of contents, may be cited as the 'Food, Drug, and Cosmetic Act Amendments of 1963.'

"TITLE I—INSPECTION AND PRODUCTION OF EVIDENCE

"EXTENSION OF PRESCRIPTION DRUG INSPECTION AUTHORITY
TO OTHER DRUGS, FOOD, COSMETICS, AND DEVICES

"SEC. 101. (a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 374(a)) is amended by—

"(6) striking out in the second sentence all beginning with the words 'In the case of any factory'

Appendix H.

down through and including the words 'shall extend to', and thus combining such sentence with the first sentence;

"(7) striking out in the same sentence the subsequent words 'prescription drugs' and inserting in lieu thereof the word 'articles';"

APPENDIX I.**Secretary's Letter to the Speaker Transmitting
H. R. 6788.****Department of
HEALTH, EDUCATION, AND WELFARE****May 29, 1963****Dear Mr. Speaker:**

There is enclosed herewith a draft bill with the short title, "Food, Drug, and Cosmetic Act Amendments of 1963" which is designed to strengthen consumer protection.

This bill would carry out certain recommendations made by President Kennedy in his Consumer Protection Message of March 15, 1962, his Health Message of February 7, 1963, and his Message on Elderly Citizens of February 21, 1963, and make certain other improvements in food and drug laws.

1. Extension and clarification of inspection authority under the Federal Food, Drug, and Cosmetic Act to determine whether food, nonprescription drugs, cosmetics, and therapeutic devices are being manufactured and marketed in accordance with the law.

On October 10, 1962, the Drug Amendments of 1962 were enacted as P. L. 87-781. Section 201 of this law provided for strengthened inspection authority with respect to prescription drugs. With certain exceptions, the amendment permits inspection of prescription drug establishments (and makes clear our authority to make inspection of independent consulting laboratories for such establishments) to encompass access to all things (including records, files, papers, processes, controls, and facilities) which have a bearing on violation of the law with respect to such drugs.

Similar authority is needed with respect to other products covered by the Food, Drug, and Cosmetic Act. Manufacturers of such products can, and a substantial number do, refuse to allow the Food and Drug Administration to make sufficient inspection of their manufacturing operations and related records to permit a sound judgment as to the legality of their operations. In the 15-month period ending March 31, 1963, 436 food firms refused to permit Food and Drug Administration inspectors to make one or more phases of inspection needed for a true evaluation of the purity and safety of the firm's output. For example, the Food and Drug Administration is hampered in determining whether poisonous ingredients are present in food and cosmetics when it is denied access to formulas. Three hundred and twenty-two of the food firms referred to above refused, for example, to furnish qualitative or quantitative formulas. And with respect to proprietary drugs, the quality control requirements for drug manufacture enacted last year would be difficult, if not impossible, to enforce unless we have inspection authority of the same scope as for prescription drugs.

Authority is also needed to make complete inspections of retail pharmacies. At present retail pharmacies are exempt from the recently broadened inspection provisions (with respect to records, etc.) relating to other establishments handling prescription drugs. Thus, the Food and Drug Administration cannot make needed investigations of the receipt and dispensing of dangerously adulterated or misbranded drugs, such as decomposed, over-age life-saving drugs, or certain other critical inspections in the retail drug store. The Food and Drug Administration should be able to review prescription files when stocks of dangerous prescription drugs are being removed from the market and when investigations are being made of druggists suspected of selling potent prescription-only drugs without prescriptions. It should also be able to inspect all other kinds of relevant pharmacy records, other than prescription files.

The enclosed bill would, therefore, extend the inspection authority presently applicable only to prescription drugs to all other products covered by the Food, Drug, and Cosmetic Act, permit the review of drugstore prescription files when the inspector has reason to believe that the pharmacy has dispensed prescription drugs intended for human use in violation of the Act's provisions governing the dispensing of such drugs, or when the inspector is tracing the distribution of dangerously adulterated drugs or devices, or of a new drug or device in violation of the new-drug section's requirements, and permit the inspection of nonprescription records of pharmacies.

Sincerely,

ANTHONY J. CELEBREZZE,
Secretary.

In the Supreme Court of the United States

OCTOBER TERM, 1966

No.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER
OF FOOD AND DRUGS, PETITIONERS

v.

/THE TOILET GOODS ASSOCIATION, INC., ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE SECOND CIRCUIT

The Solicitor General, on behalf of the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs, petitions for a writ of certiorari to review the judgment of the court of appeals insofar as it sustains the district court's denial of the petitioners' motion to dismiss the complaint.

OPINIONS BELOW

The opinion of the court of appeals (App. A, *infra*, pp. 1a-22a; II R. 72-93)¹ is reported at 360 F. 2d 677.

¹"R." designates the two-volume certified record on file in No. 336, this Term, presently pending on petition for certiorari. The record in No. 336 is also the record in this case since the

(1)

The first opinion of the district court (I R. 88-99) is reported at 235 F. Supp. 648; the second (I R. 7-14) is not yet reported.

JURISDICTION

The judgment of the court of appeals was entered on April 13, 1966 (App. B, *infra*, p. 23a; II R. 94). On July 7, 1966, Mr. Justice Stewart extended the time for filing a petition for a writ of certiorari to and including August 11, 1966. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether interpretive regulations issued by the Commissioner of Food and Drugs under the 1960 "Color Additive" Amendments to the Federal Food, Drug and Cosmetic Act may be challenged in an action for declaratory judgment.

STATUTES AND REGULATIONS INVOLVED

The relevant statutes and regulations are set forth in Appendix C, *infra*, pp. 24a-27a.

STATEMENT

In 1960, Congress adopted the "Color Additive Amendments" to the Federal Food, Drug and Cosmetic Act, 74 Stat. 397, 21 U.S.C. 321.² Insofar as per-

two cases arise from the very same proceedings; the cases differ at this stage only to the extent that each seeks review of different aspects of the judgment of the court of appeals.

We are also filing herewith a separately paginated copy of the complaint (herein "C") since a number of pages have been inadvertently omitted from the complaint contained in the certified record in No. 336.

² The paramount purpose of the amendments was to substitute the "safety-in-use" test for color additives which could not meet the test of harmlessness per se adopted by this Court in *Fleming v. Florida Citrus Exchange*, 358 U.S. 153.

continent here, the amendments provided that a cosmetic should be deemed adulterated if it is, bears or contains a color additive that has not been listed and certified as safe for its intended use by the Food and Drug Administration (except where administratively exempted from such listing and certification requirements). The amendments also prescribed the general pre-marketing standards and procedures the Food and Drug Administration was to follow for listing and certifying color additives as safe for use and provided that administrative regulations should issue to specify the conditions of safe use, including any needed tolerances or other restrictions applicable to assure safety in use of the color additives. Section 201(t)(1) of the Amendments defined a "color additive" as:

(A) * * * a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto * * *.

On January 24, 1961, the Commissioner of Food and Drugs, acting pursuant to his delegated authority to adopt regulations for "efficient enforcement" of the Act (21 U.S.C. 371(a)) and under Section 4 of the Administrative Procedure Act, gave public notice of

his intention to promulgate interpretive and procedural regulations for the administration of the "Color Additive" Amendments (26 F.R. 679). After receiving numerous comments from interested parties, including some from the respondents herein, and evaluating available data, such regulations were adopted in final form on June 22, 1963 (28 F.R. 6439; 21 C.F.R. 8.1 *et seq.*; see Appendix C, *infra*, pp. 26a-27a).

In November 1963—five months after the adoption of the regulations—respondents¹ filed a complaint in the United States District Court for the Southern District of New York under the Declaratory Judgment and the Administrative Procedure Acts (see Appendix C, *infra*, pp. 24a-25a), seeking a declaration that four of the regulations constituted an unwarranted expansion of the statutory amendments not contemplated by Congress.

In essence, three of the challenged regulations (21 C.F.R. 8.1 (f), (m) and (u)) interpreted the statutory definition of the term "color additive" to include: (1) all finished cosmetic products intended for coloring the human body (*i.e.*, lipstick, rouge, eye makeup colors and related cosmetics); (2) "all diluents"—non-pigmented materials with which colors are mixed to facilitate their use; and (3) certain hair dyes, the injurious qualities of which could not be ascertained and avoided by a simple preliminary patch test per-

¹ The Toilet Goods Association ("Toilet Goods") is a trade association of cosmetic manufacturers whose members allegedly sell in excess of 90% of the annual sales of cosmetics in the United States. The forty other respondents are manufacturers and distributors of cosmetic products (I R. 18-19).

formed by the purchaser, and which were thus, according to the administrative interpretation, not within the statutory "hair dye" exemption in Section 601(a) of the Act. The fourth regulation provided that the Food and Drug Commissioner "may immediately suspend certification service" when the manufacturer has "[r]efused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived" (21 C.F.R. 8.28(a)(4)).

After asserting that Congress did not intend that a finished cosmetic product be treated as a color additive subject to pre-marketing testing and clearance requirements (C. 6-14),^{*} the complaint alleged that the regulations threatened immediate and irreparable injury to respondents in that they either had to meet the listing and certification requirement at great financial expense, disruption of long-settled business practices, curtailment of a new product distribution, and disclosure of secret formulae and processes, or else face civil or criminal suits for non-compliance, the very institution of which would seriously injure consumer confidence in their products (C. 14-17, 19-20; 23, 25-26). Petitioners moved to dismiss asserting, *inter alia*, that the regulations were fully consonant with the Congressional purpose of insuring consumer safety in the use of "color additives" including color-

^{*} The particularized allegations challenging the validity of the regulations are summarized in the opinion of the court of appeals (App. A, *infra*, pp. 7-8).

imparting cosmetics (I R. 374-376), and that respondents were required first to exhaust their administrative remedy by providing proof of safety for use and seeking judicial review of an adverse determination if the administrative order did not permit the marketing of products which respondents considered permissible under the statute. Petitioners contended further that the regulations had no immediate impact since their application in a specific instance had not been called into operation (I R. 86).

The district court denied the motion to dismiss, finding that the complaint did set forth a justiciable controversy as to each of the challenged regulations (I R. 99).^{*} The court, however, denied respondent's motion for summary judgment and set the case down for trial. It stated that while the questions for resolution were essentially matters of statutory interpretation, expert testimony would be adduced at the trial with respect to "the technical problems involved" and "since professionally qualified representatives of both plaintiffs and defendants were present during the hearings and debates which preceded the passage of the 1960 Color Additive Amendments, it would be

^{*} In so holding, the court relied in major part on the decision in *Abbott Laboratories v. Celebrezze*, 228 F. Supp. 855 (D. Del.), where a declaratory judgment had been granted invalidating an interpretive drug-labeling regulation as exceeding the authority granted by Congress under the 1962 Drug Amendments of the Federal Food, Drug and Cosmetic Act (I R. 88-96). That decision was reversed by the Court of Appeals for the Third Circuit on the ground that the issue was not justiciable. 352 F. 2d 286. Certiorari has been granted in that case, 383 U.S. 924, No. 39, this Term.

helpful to hear their testimony relative to legislative intent, which presumably, they had an important role in shaping and assisting" (I R. 98, 96).

About a year later (after pre-trial discovery proceedings) the district court allowed petitioners to renew their motion to dismiss and for summary judgment (I R. 100-101). These motions requested the court to reconsider its ruling on the question of justiciability in light of the Third Circuit's decision in *Abbott Laboratories v. Celebrezze*, 352 F. 2d 524 (I R. 102-106), reversing the district court's holding in that case (*supra*, n. 5, p. 6), that the validity of an administrative regulation interpreting a 1962 Drug Amendment to the Federal Food, Drug and Cosmetic Act was justiciable. The Third Circuit had found the regulation not to be subject to judicial review by way of declaratory judgment (a) because the court found in the statutory scheme an intent to preclude judicial review at that juncture of the validity of that kind of regulation, and (b) because absent any agency attempt at enforcement of the regulation there was not posed the "actual controversy" required to justify relief under the Declaratory Judgment Act. After argument, the district court in this case adhered to its earlier decision (I R. 7-13).

On an interlocutory appeal under 28 U.S.C. 1292 (b) (II R. 68), the court of appeals affirmed in part and reversed in part.⁶ With respect to the three regulations interpreting the statute as requiring that

⁶ While the case was pending before it, this Court granted certiorari in *Abbott Laboratories*, No. 39, this Term.

finished cosmetics, all diluents and certain hair dyes be subject to pre-marketing listing and certification; the court held their validity raised issues of statutory construction ripe for judicial resolution. In so ruling, the court specifically rejected the argument that judicial review procedures provided by the "Color Additive" Amendments were meant to be exclusive and noted that the Third Circuit's decision in *Abbott Laboratories* could not be satisfactorily distinguished. The court did suggest, however, that if, during trial, it turned out that there was need for detailed factual evidence best produced at agency hearings, or that the agency had reduced the hardships of proceeding to review through the statutory process, the district court could refuse to enter a declaratory judgment (I R. 83-91).

As for the regulation relating to agency inspection of formulae and processes, the court found judicial intervention premature since the regulation was cast in tentative terms, no administrative action had been taken under it and, at this stage, it appeared that adequate relief was provided by a companion regulation (21 C.F.R. 8.28(b)) (II R. 91-93).

REASONS FOR GRANTING THE WRIT

The court below recognized that its views conflicted squarely with those of the Court of Appeals for the Third Circuit in *Abbott Laboratories v. Gelebrezze*, 352 F. 2d 286, in which certiorari has been granted by this Court, 383 U.S. 924, No. 39, this Term. The "ripeness" and "justiciability" issues in *Abbott Laboratories* and in the instant case are similar, and this Court's decision in *Abbott Laboratories* may control the question whether the judgment of the court of ap-

peals in this case should be disturbed. Consequently, it might be appropriate in ordinary circumstances for this Court to defer action on this petition and on the petition in No. 336 until after its decision in *Abbott Laboratories*.

On the other hand, this case involves different regulations from those involved in *Abbott Laboratories*, and a different statutory scheme for judicial review. We therefore believe it would be helpful to the Court to consider the issues presented against the background of various kinds of regulations issued under the Food, Drug and Cosmetic Act. That could be achieved if this petition and the petition in No. 336 were granted and set for argument together with No. 39.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that this petition for a writ of certiorari be granted and the case be set down for argument together with *Abbott Laboratories v. Gardner*, No. 39, this Term and with the respondents' petition in this case, No. 336, this Term.

THURGOOD MARSHALL,
Solicitor General.

FRED M. VINSON, Jr.,
Assistant Attorney General.

BEATRICE ROSENBERG,
JEROME M. FEIT,
Attorneys.

WILLIAM W. GOODRICH,
*Assistant General Counsel for Food and Drugs,
United States Department of Health, Education, and Welfare.*

AUGUST 1966.

APPENDIX A

**UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT**

No. 325—September Term, 1965

(Argued February 25, 1966. Decided April 13, 1966)

Docket No. 30261

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.; AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.; CHESEBROUGH-POND'S, INC.; CHRISTIAN DIOR PERFUMES CORP.; CLAIROL INCORPORATED; COLONIAL DAMES Co., LTD.; COTY, INC.; FA-BERGE INC.; FRANCES DENNY, INC.; THE FULLER BRUSH Co.; THE GEORGE W. LUFT Co., INC.; THE GILLETTE COMPANY; A. M. HANSEN, DOING BUSINESS AS HOUSE OF HOLLYWOOD; HARPER METHOD, INC.; HELENA RUBINSTEIN, INC.; HELENE CURTIS INDUSTRIES, INC.; HENRY/HARAN/HUTCHINGS, INC.; HERBOLD LABORATORY, INC.; JOHN H. BRECK, INC.; KOLMAR LABORATORIES, INC.; LADY LENNOX COMPANY, INC.; LEHN & FINK PRODUCTS CORPORATION; ARNOLD L. LEWIS, DOING BUSINESS AS STUDIO COSMETIC Co.; MAX FACTOR & Co.; MAYBELLINE Co.; MERLE NORMAN COSMETICS, INC.; JACK B. NETHERCUTT, DOING BUSINESS AS NETHERCUTT LABORATORIES; NEUTROGENA CORP.; NUTRILITE PRODUCTS,

INC.; OLD 97 COMPANY; PRIVATE LABEL COSMETICS Co., INC.; PURITAN COSMETICS Co.; REVLOX, INC.; ROUX LABORATORIES, INC.; SHULTON, INC.; AND YARDLEY OF LONDON, INC., PLAINTIFFS-APPELLEES

v.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS-APPELLANTS

Before WATERMAN, MOORE and FRIENDLY, *Circuit Judges*

APPEAL BY THE SECRETARY OF HEALTH, EDUCATION AND WELFARE AND THE COMMISSIONER OF FOOD AND DRUGS FROM AN ORDER OF THE DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK, HAROLD R. TYLER, JR., JUDGE, DENYING THEIR MOTION TO DISMISS OR GRANT SUMMARY JUDGMENT IN AN ACTION FOR A DECLARATION OF INVALIDITY OF FOUR FOOD AND DRUG ADMINISTRATION REGULATIONS RELATING TO COLOR ADDITIVES. AFFIRMED AS TO COUNTS 1, 2 AND 3; REVERSED AS TO COUNT 4.

ARTHUR S. OLICK (ROBERT M. MORGENTHAU, UNITED STATES ATTORNEY FOR THE SOUTHERN DISTRICT OF NEW YORK; JAMES G. GREILSHEIMER, ASSISTANT UNITED STATES ATTORNEY, OF COUNSEL), FOR DEFENDANTS-APPELLANTS

EDWARD J. ROSS (BREED, ABBOTT & MORGAN, NEW YORK, N.Y.; STEPHEN R. LANG, OF COUNSEL), FOR PLAINTIFFS-APPELLEES

FRIENDLY, *Circuit Judge.*

In July 1960, Congress added to the Federal Food, Drug, and Cosmetic Act a number of new provisions known as the Color Additive Amendments, 74 Stat. 397, 21 U.S.C. §§ 321-376. These were intended

“to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerance, under which such additives may be safely used.” H. R. Rep. No. 1761, 86th Cong., 2d Sess., 1960 U.S. Code Cong. & Ad. News 2887.

The Commissioner of Food and Drugs, to whom the Secretary of Health, Education and Welfare has delegated the Department's functions under the Act, 22 F. R. 1051 (1957), 25 F. R. 8625 (1960), held rule-making proceedings conforming to § 4 of the Administrative Procedure Act, 5 U.S.C. § 1003, and issued Color Additive Regulations, 21 C. F. R. Part 8, effective, with certain exceptions, on June 22, 1963.

The following November the Toilet Goods Association, a trade organization of cosmetic manufacturers whose members allegedly represent 90% of annual United States sales, and forty manufacturers and distributors of cosmetics brought this action against the Secretary and the Commissioner in the District Court for the Southern District of New York for a declaratory judgment that four provisions of the Regulations exceeded the authority conferred by the statute. Jurisdiction was properly predicated on 28 U.S.C. §§ 1331 and 1337. See *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921).¹ The defend-

¹ We thus do not reach the question whether § 10 of the Administrative Procedure Act, 5 U.S.C. § 1009, constitutes an affirmative grant of jurisdiction with respect to the review of federal administrative action, as the Supreme Court apparently assumed in *Rusk v. Cort*, 369 U.S. 367, 371-72 (1962) and we recently did in *Cappadora v. Celebrezze*, — F. 2d — (2 Cir. 1966). But see *Ove Gustavsson Contracting Co. v. Floete*, 278 F. 2d 912 (2 Cir.), cert. denied, 364 U.S. 894 (1960). Since 28 U.S.C. §§ 1336-40 do not require a jurisdictional amount, this question arises only in cases such as social security,

ants moved to dismiss or to strike certain portions of the complaint on various grounds, among others that the case was inappropriate for declaratory relief and that the action was an unconsented suit against the sovereign; plaintiffs cross-moved for summary judgment. In November 1964 Judge Tyler denied both motions in an opinion, 235 F. Supp. 648, relying in part on *Abbott Labs v. Celebrezze*, 228 F. Supp. 855 (D. Del. 1964), where the court had granted a declaratory judgment invalidating labeling regulations under the same statute. A year later, when the case was nearly ready for trial, the Secretary and the Commissioner renewed their motion to dismiss on the two grounds stated, arguing that a different conclusion on "the issue of justiciability" was called for by the Third Circuit's reversal of the *Abbott Laboratories* decision, 352 F. 2d 286 (1965),² and the District of Columbia Circuit's recent holding that declaratory relief was not available to challenge certain regulations adopted under the Tobacco Inspection Act, 7 U.S.C. § 714(b), *Danville Tobacco Ass'n v. Freeman*, 351 F. 2d 832 (D.C. Cir. 1965). Judge Tyler adhered to his determination but, at the defendants' request, made the necessary certification for an application to prosecute an interlocutory appeal under 28 U.S.C. § 1292(b); permission to appeal was granted by a panel of this court.

The first two counts of the complaint charge that the Regulations exceed the authority conferred by the statute in treating finished cosmetic products and all diluents—unpigmented materials with which colors are mixed—as "color additives" subject to various re-
passport and citizenship matters, where none of these sections is applicable and the jurisdictional amount required by § 1331 is not met.

² Subsequent to the argument of this appeal, certiorari was granted, 34 U.S.L. Week 3294 (March 1, 1966) (No. 824).

quirements for testing and administrative certification. The basic section of the Color Additive Amendments is § 706 of the Act, 21 U.S.C. § 376, which provides that a "color additive" shall be deemed unsafe unless it meets two conditions: * The additive must be covered by a "regulation," issued by the Secretary on a finding of suitability, which lists it for use either generally or under prescribed conditions; and it must either come from a batch certified for such use by the Secretary under appropriate regulations or have been exempted from the certification requirement.

The term "color additive," on which the controversy turns, is defined in § 201(t)(1), as a material which

(A) is a dye, pigment, or other substance made by a process of synthesis * * * or otherwise derived * * * from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto.

21 U.S.C. § 321(t)(1)

The Regulations of the Food and Drug Administration (FDA) interpret the statutory definition of color additive as including "all diluents" and state further that

A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." Reg. § 8.1(f).

* This is subject to an exception, not here important, for color additives covered by an exemption for investigational use by qualified experts, 21 U.S.C. §§ 376 (a) (2) and (f).

The term "diluent" is defined as:

any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

Reg. § 8.1(m)

The manufacturers admit that the coloring ingredient in a cosmetic is a "color additive" fully subject to both listing and certification requirements of § 706, and that a "diluent," in what they insist is the accepted definition of an inert substance used to dilute dyes and pigments, is subject to the Secretary's power to certify additives "with safe diluents or without diluents," § 706(c). They complain, however, that the Regulations' comprehensive definition of "color additive" goes beyond the reach of the statute in imposing both listing and certification requirements on finished products—like lipstick, nail polish, etc.—and non-color ingredients that were never intended to be subject to premarketing clearance, and on traditional diluents that were meant to be subject only to certification as components of dyes and pigments.

The third count of the complaint relates to provisions in the Regulations which attempt to subject hair dye products to premarketing clearance in what is alleged to be violation of the exemption recognized in the statute. The Act as passed in 1938, in defining

those cosmetics that were deemed to be adulterated, contained in § 601(a) an explicit exemption for hair dyes:

This provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing.

52 Stat. 1054

The exemption was carried forward in § 601(e) which declared that a cosmetic should be deemed adulterated "If it is not a hair dye and it bears or contains a coal-tar color other than one" from a certified batch. When Congress revised the statute in the 1960 Amendments, it left § 601(a) as it was but modified § 601(e) to read "If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe" within the meaning of § 706.

The Regulations recognized the statutory exemption where proper labeling called for use of the patch test but, armed with an expansive definition of "color additive" in § 8.1(f) which would on its face seem to include in a preparation for use on the hair any coloring ingredient as well as the finished product, proceeded to limit the exemption as follows:

The "hair dye" exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives

with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious substance in the "hair dye" is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.

Reg. § 8(u)

The manufacturers claim that the Regulations go beyond the statute in several ways: Whereas the 1938 Act literally exempted from premarketing clearance any coal-tar hair dye complying with the statutory condition of notice and the amendments did not purport to effect any change, the Regulations grant exemption only if the color additive in the hair dye substance is one whose irritating qualities would be detected by a patch test; and, contrary to the longstanding interpretation—in effect by regulation when the amendments were adopted*—which applied the exemption in its full scope to dual-purpose hair products like shampoos, rinses and tints with a coal-tar coloring component, the Regulations seem to limit the exemption to the coloring ingredient itself.

* Reg. § 1.200 apparently defined the term "coal-tar hair dye" in the § 601(a) exemption to include "all articles containing any coal-tar color." This definition of hair dyes was deleted by the Commissioner as superseded by § 8.1(u) of the Color Additive Regulations. 28 F.R. 10688. (1963).

Count 4 of the complaint attacks a section of the Regulations, § 8.28(a)(4), which states that when it appears to the Commissioner that a person has refused to permit duly authorized employees of the FDA "free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived," he may suspend certification service to such person until adequate corrective action is taken. The first sentence of § 704(a) of the Act, applicable to all goods, drugs, devices, or cosmetics subject thereto, authorizes the Secretary to inspect any "factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labelling therein"; the second sentence, dealing only with places where prescription drugs are manufactured, processed or held, provides for inspection extending "to all things therein (including records, files, papers, processes, controls, and facilities)." The manufacturers say the challenged regulation illegally extends to cosmetics the broadened inspection authorized only for prescription drugs, and improperly subjects trade secrets to exposure.

The expanded definition of "color additives," the narrowing of the hair dye exemption, and the allegedly compelled disclosure of secret formulae and processes impose, the manufacturers claim, burdens not contemplated by the statute and threaten immediate and irreparable injury. Even though coloring ingredients have been properly pretested, listed and certified in compliance with the statutory clearance scheme, the regulations require filing a separate listing application for each finished product, traditional diluent and non-color ingredient, including those formerly exempted under the hair dye provision; each

application must be accompanied by a \$2,600 filing fee, Reg. § 8.50(c), and supported by extensive scientific tests establishing suitability for intended use, Reg. § 8.4(c). Even after listing, every ingredient and finished product must come from a certified batch unless the Secretary has granted an exemption; a minimum fee of \$100 is charged for each certification, Reg. § 8.51(a). An affidavit by one manufacturer claimed that the listing of its finished products alone for the issuance of regulations would entail filing fees of \$7,000,000 and testing costs of nearly \$42,000,000, and that certification fees for a single year would amount to \$750,000.* Beyond such out-of-pocket costs, increased by substantial additional expenses for record-keeping, compliance with the challenged regulations, by requiring significant changes in established business practices and curtailing distribution of new products, allegedly would cause major and costly disruption of the cosmetic industry. Moreover, the disclosure of formulae and processes necessary to meet the new listing requirements and to avoid loss of certification for refusing inspection allegedly would result in misappropriation of trade secrets and discourage research and development of improved cosmetic products.

Failure to comply with the challenged regulations could have serious consequences if they are valid. Under § 601 of the Act, a cosmetic other than a hair dye is deemed adulterated if "it is, or it bears or contains, a color additive which is unsafe" within the meaning of § 706(a). Projection of any adulterated

* Very likely these figures are exaggerated since they take no account either of the FDA's power to require information on diluents as a condition of approving coloring ingredients and granting certification or of the likelihood of exemption from certification.

article into the stream of interstate commerce and refusal to allow inspection required by § 704 are prohibited acts under the statute, and are subject to injunction and entail criminal liability, §§ 301-303; and any adulterated article may be seized under § 304. The manufacturers say that, apart from all else, the publicity incident to criminal or civil proceedings against them for failure to comply with the Regulations would be seriously detrimental in a highly competitive industry which spends millions in cultivating public good will and is dependent on consumer confidence in the integrity of its products.

The Secretary and the Commissioner respond that the fears as to the dilemma posed by the Regulations are exaggerated. They insist that the Regulations merely expound the manner in which they intend to construe the amendments, that nothing has yet been done to apply the provisions of which plaintiffs complain, and that ample opportunity to test the Regulations in concrete fact situations is afforded by the path for review spelled out in the statute. If the manufacturers will only comply with the listing and certification requirements, the FDA's application of the statute will, under § 706(d), be subject to the general administrative provisions on hearings and review in § 701. Since the review authorized in § 706(d) is directed at decisions approving or disapproving listing and certification and §§ 701 (e) and (f) are limited to review of other specifically enumerated agency determinations, the contention is not that the statutory provisions afford a direct path to review of the general regulations on listing requirements; it is rather that they furnish an indirect but nevertheless sufficient one which the manufacturers ought to have taken. The proper course, defendants say, is for a manufacturer to petition for the listing of dilu-

ents and finished cosmetic products as color additives, while protesting against the need for doing so and conforming with the detailed requirements for filing information only to the extent he believes proper under the statute; such a petition could be accompanied by a request for exemption from batch certification, again with appropriate protest and non-compliance with the requirement of factual data to support the application. Either the FDA would retreat from applying its announced interpretation of the statute and grant the petition and the request for exemption, or it would deny them, which event the road to a court of appeals would be open under §§ 701 (e) and (f).

II

The serious questions* are whether direct challenge of the Regulations by suit in a district court is impliedly barred by the availability of review of listing and certification denials in a court of appeals, and whether the controversy is appropriate for judicial determination prior to application of the Regulations in a particular factual situation.

We are not persuaded that by providing a procedure for review of certain administrative decisions under the Food and Drug Act in the courts of appeals, Congress meant to foreclose relief with respect to

* We need not discuss in the text the surprising contention that an action for a declaration that federal regulatory officers have acted in excess of their authority constitutes an unconstitutional suit against the United States. The contrary is clearly established by *Philadelphia Co. v. Stimson*, 223 U.S. 605, 619-20 (1912), see *Stark v. Wickard*, 321 U.S. 288, 290 (1944), and indeed follows inevitably from *Ex parte Young*, 209 U.S. 123 (1908); law officers of the Government ought not to take the time of busy judges or of opposing parties by advancing an argument so plainly foreclosed by Supreme Court decisions.

other agency action under the Administrative Procedure Act § 10, 5 U.S.C. § 1009, or the Declaratory Judgement Act, 28 U.S.C. § 2201, in a case where this would otherwise be appropriate. The agency determinations specifically reviewable under § 701(e) relate to such technical subjects as chemical properties of particular products and the formulation and application of safety standards for protecting public health; Congress naturally did not wish courts to consider such matters without the benefit of the agency's views after an evidentiary hearing before it. Section 701, however, also contemplated other less specialized administrative action by authorizing, in subsection (a), the making of regulations for the efficient enforcement of the statute, and it expressly declared in subsection (f) that the provision for review of certain orders in the courts of appeals was "in addition to and not in substitution for any other remedies provided by law." 21 U.S.C. § 371(f)(6). The section as a whole does not indicate to us any congressional intent either to insulate administrative action not covered by subsection (e) from challenge as in excess of statutory authority, see *Stark v. Wickard*, 321 U.S. 288, 308-11 (1944); cf. *Cappadora v. Celebrezze*, 356 F. 2d 1, 5 (2 Cir. 1966); or to postpone immediate challenge to such action where awaiting the issuance of adjudicative orders subject to statutory review would provide less effective relief. Insofar as *Abbott Labs. v. Cele-*

The legislative history of the 1938 Act suggests that Congress had no intention of limiting review of other action by adopting a special procedure for the enumerated determinations. The House Report, referring to the savings clause in § 701 (f)(6), stated:

There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the

brezze, 352 F. 2d 286, 289 (8 Cir. 1965), cert. granted, intimates otherwise, we are unwilling to follow it.

The question whether a plaintiff may obtain judicial relief in cases like this has been variously phrased as whether he has "standing" to challenge the administrative action as a person "suffering legal wrong" or "aggrieved" within the meaning of § 10 of the APA, whether the dispute is an "actual controversy" within the Declaratory Judgment Act, or whether it is sufficiently "ripe" for resolution by the courts. See Jaffe, *Judicial Control of Administrative Action* 395-98 (1965). In fact, the critical issue is apt to be less a matter of standing or of actual controversy than of the advisability of reviewing an administrative rule prior to its application in a specific factual situation. The current healthy trend toward implementing agency policy by rule-making cuts both ways with respect to declaratory relief—increasing the need for this sort of assistance on the part of those subjected to such rules, see *Columbia Broadcasting Sys., Inc. v. United States*, 316 U.S. 407, 421 (1942), but also creating a danger that, unless the courts are circumspect, administration may be improperly halted, at least temporarily, before it

enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.

H.R. Rep. No. 2139, 75th Cong., 3d Sess., p. 11 (April 14, 1938).

The accompanying minority report, in endorsing the Secretary's challenge to the new review provisions as jeopardizing enforcement of the statute, indicated that the special procedure was understood to be an additional protection for industry and not an exclusive method of review of all actions for the benefit of the agency. H.R. Rep. 2139, Pt. 2 (April 21, 1938).

has gotten the slightest start.* The problem is not to be solved, as the parties suggest, by applying some readily procurable litmus paper which will determine whether a controversy is "justiciable"; what is required, as in the case of challenge to the constitutionality of a statute, is a reasoned evaluation of "both the appropriateness of the issues for decision by courts and the hardship of denying judicial relief." *Joint Anti-Fascist Refugee Comm. v. McGrath*, 341 U.S. 123, 156 (1951) (*Frankfurter, J.*, concurring); see *Jaffe, supra*, at 396, 423.

The appropriateness of passing judgment on the validity of an administrative regulation prior to its application to particular facts depends on such factors as how far the rule represents the definitive position of the agency and the extent to which the challenge raises a clearcut legal issue susceptible of judicial solution without reference to fact variables arising in its implementation. Cf. *Northeast Airlines, Inc. v. CAB*, 345 F. 2d 662, 664. (1 Cir. 1965). Review might be considered premature where an agency rule had not received substantially as full consideration in its formulation as it would have in subsequent application, or where future experience would be likely to result in significant modifications as to its

* The danger of unwarranted postponement of the effectiveness of agency action is augmented by the fact that a suit for declaratory relief must be brought in a district court, twice removed from the supreme tribunal, whereas adjudicative orders are generally reviewable either in courts of appeals or in specially constituted district courts from which appeal lies directly to the supreme court. Yet here too there is another side; a district court may be in a better position than a court of appeals to carry out fact finding, as Congress recognized in the Hobbs Act, 5 U.S.C. § 1087(b).

precision or scope. Judicial determination might also be deemed inappropriate where the controversy over the rule did not present a legal issue that a court was qualified to resolve without reference to factual determinations more effectively made by the agency familiar with day to day administration. See Jaffe, *supra*, at 406. In this case, however, the Regulations under attack were issued after a full hearing with notice and by their terms represent the definitive agency position on the reach of the statutory requirements for listing and certification of cosmetics, see *Columbia Broadcasting Sys., Inc. v. United States*, *supra*, 316 U.S. at 422; *United States v. Storer Broadcasting Co.*, 351 U.S. 192, 198 (1956); to the extent that they purport to apply premarketing requirements to broad categories like finished products and noncoloring ingredients and define the hair-dye exemption, they appear, *prima facie*, to be susceptible of reasoned comparison with the statutory mandate without inquiry into factual issues that ought to be first ventilated before the agency. Indeed, it is manifest that if the manufacturers adhere to their legal position, *pro forma* individual applications to the FDA for listing and certification would produce a record no more, and very likely less, illuminating than what the district court will develop at trial of this action in which the great bulk of the industry is represented and will be bound. The mere fact that the procedure which the defendants suggest would bring the issue directly to a court of appeals without prior resort to a district court, while entitled to some weight, is not controlling. As indicated earlier, the statutory procedure for review of individual determinations in the courts of appeals was not intended as a means for challenging FDA rule-making of the usual sort; as shown by the authorities discussed below, the mere fact that pursuit of that course could

produce a decision on legal issues similar to that here sought does not make its use mandatory..

With respect to the other relevant consideration, the degree of hardship warranting declaratory relief, although some older precedents suggest broadly that an administrative ruling is not reviewable until and unless it imposes an obligation or subjects the plaintiff to some civil or criminal liability, see, e.g., *United States v. Los Angeles & Salt Lake R.R.*, 273 U.S. 299, 309-10 (1927); *Shannahan v. United States*, 303 U.S. 596, 599 (1938), there has been a growing recognition that the timeliness of review depends on a broader concept of the substantiality of present or immediate harm. See 3 Davis, *Administrative Law Treatise* § 2107 (1958). In *Columbia Broadcasting Sys., Inc. v. United States*, 316 U.S. 407, 417-21 (1942), the Supreme Court declared that though a particular rule does not of itself deny a license or directly impose sanctions, it may nevertheless be reviewable if it establishes a general standard of conduct which by its very promulgation demands conformity and poses, for the plaintiff or others with whom he must deal, the alternatives of compliance or severe penalties of forfeiture or disruption of business operations. In *Frozen Food Express v. United States*, 351 U.S. 40, 43-44 (1956), the Court recognized that an agency order generally announcing the scope of administrative regulation was subject to immediate frontal attack, although opportunities for later challenge were sure to come from a cease and desist order by the ICC, see *Eastern Texas Motor Lines v. Frozen Food Express*, 351 U.S. 49 (1956), or suit for an injunction by the agency or competitors.* And in *United*

* If it be said that the carrier was subject to liability for criminal penalties even before a cease and desist order or an injunction, the same is true here.

States v. Storer Broadcasting Co., 351 U.S. 192, 199-200 (1956), declaratory rules setting limits on the number of licenses to be granted for broadcasting stations under common ownership were held to be immediately reviewable because they operated "to control the business affairs" of the plaintiff and made it impossible to "cogently plan its present or future operations" so long as their validity remained undetermined; direct challenge to the regulations was permitted even though review might have been obtained by provoking an adverse administrative order, see 351 U.S. at 208 (dissenting opinion).¹⁰ See also *Flemming v. Florida Citrus Exch.*, 358 U.S. 153, 168 (1958).

We see little profit in debating the point, much discussed by the parties, whether the Regulations are "interpretative" or "legislative." Although that issue

¹⁰ In fact the FCC dismissed the plaintiff's application for an additional station on the basis of the new rules the very day they were adopted, 351 U.S. at 197, but review of the particular decision was not sought.

We recognize that in *Storer* review of the rule was in the Court of Appeals for the District of Columbia, the same tribunal to which *Storer* would have gone for review of the denial of an application; but the dissenters thought the rationale of the majority would support a suit for declaratory relief in a district court after the 60-day limitation for seeking review by the Court of Appeals had expired, 351 U.S. at 210 (dissenting opinion of Harlan, J.). A more important differentiating consideration may be that awaiting denial of a future application may not have afforded a broadcaster who had reached the ceiling so full an opportunity for challenge as might appear at first blush; if the application was a competitive one for a new license, the FCC might predicate denial on other grounds, and to negotiate a transfer of an existing license in the teeth of the multiple-ownership rules would be of dubious business practicability. However, this ground for distinguishing *Storer* would not apply to *Frozen Food Express*.

would-have to be faced if the FDA had failed to comply with the rule-making procedures of § 4 of the APA because of a claim on its part that the Regulations were merely "interpretative," the interpretative character of a regulation does not necessarily make it unripe for review; we perceive no reason why a rule whereby an agency subjects to regulation activities contended to be immune should be exempt from immediate review because it purports to interpret a statute although it would not be if made in the exercise, contended to be illegal, of a substantive rule-making power. See *Frozen Food Express v. United States*, *supra*; Jaffe, *Judicial Control of Administrative Action* 405-07 (1965); and 1 Davis, *Administrative Law Treatise* § 5.03 (1965 Pocket Part), criticizing on this ground *American President Lines, Ltd. v. FMC*, 316 F. 2d 419 (D.C. Cir. 1963), on which defendants rely. Neither do we think anything is to be gained by an attempt at comprehensive review of the decisions; the many cases in this area are not truly reconcilable and the law has been moving in the direction of greater freedom of review, see Jaffe, *supra*, at 412-17 (which, *inter alia*, criticizes another decision relied on by defendant, *Helco Prods. Co. v. McNutt*, 137 F. 2d 681 (D.C. Cir. 1943)); and 3 Davis, *Administrative Law Treatise* §§ 21.06-21.08 (1958). We limit ourselves to the two recent Court of Appeals decisions which defendants most strongly urge upon us.

Danville Tobacco Ass'n v. Freeman, 351 F. 2d 832 (D.C. Cir. 1965), was a rather weak case for declaratory relief. The plaintiffs there were neither threatened with penalties nor, like those in *Frozen Food* and here, faced with the need of applying for licenses to permit continuation of an established business; moreover, there was no showing that the challenged regulation was in fact preventing expansion of their

operations, since they had filed no applications and petitions by other applicants had been denied on grounds other than those attacked. Agreeing with the defendants that *Abbott Labs v. Celebrezze*, 352 F. 2d 286 (3 Cir. 1965), cert. granted, is not distinguishable on any satisfying basis, we must confess, with all respect, our inability to understand why the plaintiffs there should be required to violate the challenged FDA regulation in order to raise the same legal issue as to which the district court had granted declaratory relief. Insofar as the *Abbott* decision rested on a negative implication from the limited review provisions of the Food and Drug Act, we have already noted our inability to agree.

III.

In applying the general considerations thus developed to the precise issues here presented, we must bear in mind that this appeal is not from a declaratory judgment but from the denial of a motion to dismiss a complaint seeking one. The issue on such an appeal is not whether the grant of a declaratory judgment was in fact appropriate but whether it so clearly would not be that dismissal *in limine* was required.

As regards the counts of the complaint challenging the inclusion of finished products and color additives and the alleged restrictions of the hair-dye exemption, the appeal must fail. These Regulations appear to have an immediate impact on the industry, posing the unacceptable alternatives of complying or of incurring possible forfeitures and criminal liability, and calling into question long standing practices of pre-marketing testing and clearance. The issues framed by the counts of the complaint addressed to these Regulations appear sufficiently suitable for immedi-

ate judicial resolution and the threatened harm sufficiently great, that the district court properly declined to dismiss them. If the court should find that the issues are not susceptible of resolution without detailed factual evidence that ought to be first sifted by the agency, or that measures being taken by the FDA for the listing and exemption from certification of approval diluents have so reduced the hardship on the plaintiffs as to make declaratory relief inappropriate, it need not proceed to judgment. But, so far as we can now see, the sooner the industry's claims as to the coverage of the Act in these respects are determined, the better for everybody. As said in Jaffe, *Judicial Review of Administrative Action* 404 (1965), "The public has an interest in early implementation of policy; the regulated person has a legitimate interest whether to plan or not to plan his operation." Moreover, the party disappointed by court decision may wish to take the case to Congress.

The fourth count of the complaint, relating to agency inspection of formulae and processes, stands differently. Here the challenged regulation, §8.28(a) (4), does not of itself demand compliance at the expense of penalties. A manufacturer who refuses access to his trade secrets is not threatened with criminal liability or seizure; the regulation does not suggest that such refusal will be deemed a "prohibited act" under the statute, as it would be in the case of prescription drugs. It simply warns the industry that the Commissioner may—not that he inevitably will—consider a refusal to permit such inspection a sufficient cause for suspending certification. Moreover, the next paragraph §8.29(b), says that upon receipt of notice of suspension, the person so notified may request a hearing upon the factual basis therefor. If after such hearing the Commissioner should adhere to

his refusal to certify, review by a court of appeals would seem available under §§706(d) and 701(f); if not, an action could be brought in the district court.

In this instance the possibility of unlawful injury to the plaintiffs is, on its face, too remote for declaratory relief. No one can now say whether the Commissioner will ever make a demand for free access to color additive processes or formulae, whether any manufacturer will ever decline this, what the Commissioner would do if so refused, and what result a hearing would have. The fact that the Commissioner's proclamation of the possible consequences of refusal may induce manufacturers to be more compliant than if he had kept silent until an episode calling for action arose is not a sufficient basis for declaratory relief. Moreover, it is impossible to see what declaration a court could properly make. No one could reasonably assert that circumstances warranting suspension of certification if a manufacturer refused to give the FDA information concerning processes or formulae could never arise; Congress' failure to empower the agency to compel an inspection of processes of formulae is not a mandate to grant certificates when the public cannot properly be protected otherwise. Review of this Regulation should be on a case by case basis and with a factual record to assist in determining whether access to secret processes and formulae is necessary and appropriate to performance of the task of effective premarketing clearance in a particular instance—at least in the absence of experience showing consistent abusive tactics.

The judgment with respect to Count 4 is reversed with instructions to grant the motion to dismiss; the judgment with respect to Counts 1, 2, and 3 is affirmed, with further proceedings to be promptly taken in the district court in accordance with this opinion.

APPENDIX B

JUDGMENT OF THE COURT OF APPEALS FOR THE SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Courthouse in the City of New York, on the thirteenth day of April one thousand nine hundred and sixty-six.

Present: Hon. Sterry R. Waterman, Hon. Leonard P. Moore, Hon. Henry J. Friendly, Circuit Judges.

**THE TOILET GOODS ASSOCIATION, INC., ET AL.,
PLAINTIFFS-APPELLEES,**

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, AND GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS-APPELLANTS

Appeal from the United States District Court for the Southern District of New York.

This cause came on to be heard on the transcript of record from the United States District Court for the Southern District of New York, and was argued by counsel.

ON CONSIDERATION WHEREOF, it is now hereby ordered, adjudged, and decreed that the order of said District Court be and it hereby is affirmed as to the First, Second and Third Counts of the complaint.

It is further ordered that the order of said District Court be and it hereby is reversed as to the Fourth Count of the complaint with instructions to grant the motion to dismiss in accordance with the opinion of this court.

A. DANIEL FUSARO,
Clerk.

APPENDIX C

1. The Federal Declaratory Judgment Act, 28 U.S.C. 2201, provides, in pertinent part:

Creation of remedy

In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. * * *

Section 10 of the Administrative Procedure Act, 60 Stat. 243, 5 U.S.C. 1009, provides in pertinent part:

Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

(a) **RIGHT OF REVIEW.**—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action, within the meaning of any relevant statute, shall be entitled to judicial review thereof.

(b) **FORM AND VENUE OF ACTION.**—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial re-

view in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

(c) **REVIEWABLE ACTS.**—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority.

Section 201(t)(1) of the 1960 "Drug Additive" amendments to the Federal Food, Drug and Cosmetic Act, 74 Stat. 397, 21 U.S.C. 321(t)(1) provides:

The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation,

determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

21 C.F.R. 8.1(f) provides in pertinent part:

A "color additive" is any material, not exempted under section 201(t) of the act * * *. This includes all diluents. * * *. A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are color additives. * * *

21 C.F.R. 8.1(m) provides:

The term "diluent" means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

21 C.F.R. 8.1(u) provides:

The "hair dye" exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious sub-

stance in the "hair dye" is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.

21 C.F.R. 8.28(a)(4) provides:

(a) When it appears to the Commissioner that a person has:

* * * * *

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived; he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

Also, similar questions of "ripeness" and "justiciability" are involved in *Abbott Laboratories v. Gardner*, in which this Court has granted certiorari, 383 U.S. 924, No. 39, this Term. In these circumstances, while we believe that the court of appeals rendered the correct decision on the question presented by the instant petition,¹ we agree that it would be appropriate either to defer consideration of this petition until after the decision in *Abbott Laboratories v. Gardner* or to grant this petition and our cross-petition so that the Court may consider the issues presented in the varying factual contexts.

Respectfully submitted.

THURGOOD MARSHALL,
Solicitor General.

AUGUST 1966.

¹The challenged regulation provides that the Food and Drug Commissioner "may immediately suspend certification service" of a color additive when the manufacturer has "[r]efused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived" (21 C.F.R. 8.28(4)). The court of appeals held that review was premature since the regulation "simply warns the industry that the Commissioner may—not that he inevitably will—consider a refusal to permit such inspection a sufficient cause for suspending certification" (360 F. 2d at 687) and since a companion regulation (21 C.F.R. 8.28(b)) provides for an administrative hearing on the propriety of the withdrawal of certification. Review may presumably be had in the court of appeals if the commissioner were to insist upon withdrawing certification (Pet. App. A, pp. 1-21).

In the Supreme Court of the United States

OCTOBER TERM, 1966

No. 336

THE TOILET GOODS ASSOCIATION, INC., ET AL.,
PETITIONERS

v.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER
OF FOOD AND DRUGS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED
STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

MEMORANDUM FOR THE RESPONDENTS

Petitioners seek review of that portion of the judgment of the court below (Pet. App. A 1-20; 360 F. 2d 677) holding declaratory relief unavailable at this juncture to test the statutory validity of a regulation of the Food and Drug Administrator interpreting the 1960 "Color Additive" amendments to the Federal Food, Drug and Cosmetic Act.

The government has petitioned for a writ of certiorari to review the same judgment insofar as it held other Food and Drug regulations ripe for review.



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In the Supreme Court of the United States

OCTOBER TERM, 1966.

No. 336

**THE TOILET GOODS ASSOCIATION, INC., ET AL.,
PETITIONERS**

v.

**JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, AND JAMES L. GODDARD, COMMIS-
SIONER OF FOOD AND DRUGS**

No. 438

**JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, AND JAMES L. GODDARD, COMMIS-
SIONER OF FOOD AND DRUGS, PETITIONERS**

v.

THE TOILET GOODS ASSOCIATION, ET AL.

**ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF
APPEALS FOR THE SECOND CIRCUIT**

**BRIEF FOR RESPONDENTS IN NO. 336 AND FOR PETITIONERS
IN NO. 438**

OPINIONS BELOW

The opinion of the court of appeals (R. 119-138) is reported at 360 F. 2d 677. The first opinion of the district court (R. 67-76) is reported at 235 F. Supp. 648; the second (R. 48-53) is not reported.

JURISDICTION

The judgment of the court of appeals was entered on April 13, 1966 (R. 138-139). The petition for a writ of certiorari in No. 336 was filed on July 12, 1966. On July 7, 1966, Mr. Justice Stewart extended the time for filing a petition in No. 438 to and including August 11, 1966 (R. 140), and the petition was filed on that date. Both petitions were granted on October 10, 1966 (R. 141, 142). The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether certain interpretive regulations issued by the Commissioner of Food and Drugs for the enforcement of the 1960 "Color Additive" Amendments to the Federal Food, Drug and Cosmetic Act may be challenged prior to their enforcement in an action seeking declaratory and injunctive relief.

STATUTES AND REGULATIONS INVOLVED

The relevant statute and regulations are set forth in the Appendix, *infra*, pp. 23-38.

STATEMENT

In 1960 Congress enacted the Color Additive Amendments (74 Stat. 397, 21 U.S.C. 321) to the Federal Food, Drug and Cosmetic Act of 1938. Insofar as pertinent here, these amendments provide that a cosmetic shall be deemed adulterated if it is, or it bears or contains a "color additive" that has not been listed and certified as safe for its intended use under regulations to be issued by the Secretary (except where the additive has been administratively exempted from such certification requirements) (Sec-

tions 706 (a), (f), pp. 29, 34, *infra*). The amendments detail the pre-marketing standards the Food and Drug Administration is to apply in determining whether color additives will be safe for use (Sec. 706(b), p. 31, *infra*), and provide that administrative regulations should issue to specify the conditions of safe use, including any needed tolerances or other restrictions applicable to assure safety in use (Sections 706(b)(3), 706(c), pp. 29, 32, *infra*).

Section 201(t)(1) of the Food, Drug and Cosmetic Act, as amended in 1960, defines a "color additive" as:

(A) * * * a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto * * *

On June 22, 1963, the Commissioner of Food and Drugs under delegated authority from the Secretary promulgated interpretive and procedural regulations for the administration of the Color Additive Amendments (28 Fed. Reg. 6439, 21 C.F.R. 8.1 *et seq.*; see pp. 34-35, *infra*).¹ Four of those regulations are

¹ About a year and a half earlier, on January 24, 1961, the Commissioner of Food and Drugs had given public notice of his intent to adopt such regulations and had offered an opportunity for all interested persons to present their views in writing (26 Fed. Reg. 679). Numerous comments, including some from the plaintiffs in this suit, were submitted and evaluated before the regulations were issued.

challenged in this lawsuit. Two (21 C.F.R. 8.1(f), and (m)) interpreted the statutory definition of "color additive" to include: (1) all finished cosmetic products intended for coloring the human body (i.e., lipstick, rouge, eye makeup colors and related cosmetics) and (2) all "diluent"—non-pigmented materials with which colors are mixed to facilitate their use in food, drugs, cosmetics and for coloring the human body. The third (21 C.F.R. 8.1(u)) provided that "hair dyes", the injurious qualities of which could not be ascertained by the patch test required by Section 601(a) of the Act, were not within the "hair dye" exemption granted by the statute. The fourth provided that the Food and Drug Commissioner "may immediately suspend certification service" when the manufacturer has "[r]efused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived" (21 C.F.R. 8.28(2)(4)).²

In November 1963, respondents³ filed a complaint in the United States District Court for the Southern

² Subsection (b) of 21 C.F.R. 8.28—the validity of which is not challenged—provides that "[u]pon receipt of the notice of suspension of service, the person so notified may request a hearing upon the factual basis for the suspension." See 21 C.F.R. 130.14–130.26, 130.31.

³ For the sake of clarity the respondents in No. 438 (who are also the petitioners in No. 336) are hereinafter referred to as "respondents", and the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs are throughout referred to as the "petitioners". The Toilet Goods Associa-

District of New York under the Declaratory Judgments Act and the Administrative Procedure Act seeking injunctive relief and a declaration that the four regulations constituted an unauthorized interpretation of the statutory amendments (R. 1-43). The complaint alleged that Congress had not intended in the Color Additive Amendments to subject all finished cosmetic products, all diluents and certain hair dyes to the pre-marketing listing and certification requirements of the statute and that it did not contemplate that the factory inspection provisions of the Act (Section 704, 21 U.S.C. 374, p. 34, *infra*) would extend to the formulae and manufacturing processes for cosmetics. The complaint also alleged that the regulations threatened immediate and irreparable injury to respondents in that they either had to meet the requirements of listing, testing and certification or exemption from certification at great financial

tion is a trade association of cosmetic manufacturers whose members are said to produce in excess of 90% of the annual sales of cosmetics in the United States. The forty other respondents are ~~manufacturers~~ and distributors of cosmetic products.

Throughout this litigation there has been a dispute between the parties as to the coverage of the finished cosmetic product and diluent regulations. Respondents have claimed throughout that the regulations in effect, establish a pre-marketing licensing system for *all* cosmetic products and ingredients. It is the view of the Food and Drug Administration that the regulations have a more limited scope, applying in terms only to those cosmetics that impart color to the human body and only to those diluents which actually function to facilitate the use of the pure color materials in the product in which such materials are used. As for cosmetics which do not impart color to the human body (such as perfume), the Food and Drug Administration does not require pre-marketing licensing, but only proof of safety of the color ingredients for their intended use.

expense, disruption of long-settled business practices, curtailment of new product distribution, and disclosure of secret formulae and processes, or else face civil or criminal suits for noncompliance. It was alleged that the institution of such proceedings would seriously injure consumer confidence in respondent's products (R. 21-26; 29-31; 37-38; 41).

Petitioners moved to dismiss (R. 53-67) asserting, *inter alia*, that the regulations were consistent with the Congressional purpose of insuring consumer safety in the use of color additives and that judicial review at this juncture was inappropriate and not authorized by any statute, including the Declaratory Judgments Act.

The district court denied the motion to dismiss, finding that the complaint did set forth a controversy as to each of the challenged regulations (R. 67-76.) The court also denied respondents' motion for summary judgment, however, and set the case for trial. Although the questions presented involved, in the court's view, essentially matters of statutory interpretation, expert testimony was believed helpful on "the technical problems involved" (R. 75). The court also stated that "since professionally qualified representatives of both plaintiffs and defendants were present during the hearings and debates which preceded the passage of the 1960 Color Additive Amendments it would be helpful to hear their testimony relative to legislative intent, which, presumably, they had an important role in shaping and assisting" (*ibid.*).

About a year later (after pre-trial discovery proceedings), the district court permitted petitioners to renew their motions to dismiss and for summary judg-

ment (R. 76-77). These motions requested the court to reconsider its ruling on the issue of justiciability, *inter alia*, in light of the Third Circuit's decision in *Abbott Laboratories v. Celebrezze*, 352 F. 2d 286, reversing, *per curiam*, 228 F. Supp. 855 (D. Del.), which held that the validity of administrative regulations interpreting certain provisions of the 1962 Drug Amendments to the Federal Food, Drug and Cosmetic Act were not subject to review by way of declaratory judgment in advance of a specific enforcement case (R. 76-80). The district court in this case adhered to its prior ruling, but it certified an interlocutory appeal under 28 U.S.C. 1292(b) to the Court of Appeals for the Second Circuit (R. 46-53).

The court of appeals affirmed in part and reversed in part (R. 119-139).⁵ With respect to the three regulations interpreting the statute as requiring that color-imparting cosmetics, diluents and certain hair dye be subject to pre-marketing listing and certification, the court held the question of their validity ripe for judicial resolution (R. 136-137). In so ruling, the court expressly rejected the Third Circuit's conclusion in *Abbott Laboratories* that the judicial review procedures specifically provided by the Food, Drug and Cosmetic Act were meant to be exclusive procedures to obtain pre-enforcement review (R. 135-136). With respect to the regulation relating to inspection of formulae and processes, the court found judicial review premature at this stage since that regulation was cast in permissive terms, no action had

⁵ While the instant case was *sub judice* in the court of appeals, this Court granted certiorari in *Abbott Laboratories v. Gardner*, 383 U.S. 924, No. 39, this Term.

been taken or threatened thereunder, it appeared that adequate relief by way of a hearing and judicial review were authorized by other regulations if the provision were in fact invoked, and protection of the public interest required that review of this regulation "be on a case by case basis and with a factual record . . ." (R. 137-138).

INTRODUCTION AND SUMMARY

The instant case, on its face, raises issues of justiciability closely akin to those discussed in some detail on our brief in *Abbott Laboratories v. Gardner*, No. 39, this Term. We believe that the regulations being challenged here, like those at issue in *Abbott Laboratories*, are not of the kind which the Congresses enacting the Food, Drug and Cosmetic Act of 1938 and Color Additive Amendments of 1960 intended to leave open to pre-enforcement judicial review. In the present case, as in *Abbott Laboratories*, "interpretive" regulations are involved, and they merely announce, in advance of enforcement, certain categories of products to which the Food and Drug Administration believes the Color Additives Amendments applicable. And here, as in *Abbott Laboratories*, we believe that an evaluation of "ripeness" factors warrants the conclusion that, entirely apart from the Food, Drug and Cosmetic Act itself, it would be premature for the courts to pass, at this juncture, on the claims made by respondents.

Before briefly elaborating these two points, we think it essential, however, to point out what this case does not involve. Variants in expression in re-

spondents' complaint and certain discussion in their brief in the court of appeals appear to draw into this litigation a challenge to a much more fundamental exercise of authority by the Food and Drug Administration which, we submit, is not presented by the complaint and by the narrow issues actually before the district court.

The Color Additive Amendments of 1960 were enacted, in part, to modify the former color provisions as they had been construed by this Court in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153. In the *Florida Citrus* case this Court, at the government's urging, had read the 1938 provisions (which applied only to coal-tar colors) as empowering the Food and Drug Administration to list and certify as permissible for use in foods, drugs and cosmetics only such coal-tar colors as are "harmless"; it rejected the claim that the 1938 Act imposed on the Administrator the duty, or gave him the authority, to determine whether each coal-tar color was harmful as used—i.e., "taken in a particular way and in particular quantities" (358 U.S. at 163). The 1938 Act, in other words, was read as requiring that the coal-tar colors, in and of themselves, be examined, and that, if harmless, they be listed and certified for unrestricted use. The effect of the Act was to prohibit any use whatever of colors which exhibited poisonous properties in doses larger than those which might actually be used. Industry representatives, who had been urging amendments to the color provisions for some time,

thereafter pressed the Congress to adopt a "safety-in-use" test which would permit the use of color additives wherever, in the context of their particular use, they could be shown to be harmless.

To meet the criticisms of the color industry while retaining comprehensive consumer protection, the Secretary recommended to Congress the substantial overhaul of the color provisions which ultimately took the form of the Color Additive Amendments of 1960. That statute applied safety pre-clearance conditions to all natural and synthetic colors (not just coal-tar colors) and directed a re-evaluation of the safety of all colors, including those which had been in use for a long time. In addition, and what is particularly relevant here, the statute broadly delegated to the Commissioner the authority either to list and clear a color for unrestricted use or to permit "more limited use or uses * * * for which it is suitable and may safely be employed" and to "prescribe the conditions under which [it] may be safely employed for such use or uses * * *." Section 706(b), 21 U.S.C. 376(b), p. 30, *infra*. In determining whether and how to permit use for limited purposes of a color which could not be deemed "harmless" the Commissioner was directed to consider at least four factors specifically enumerated in Section 706 (b)(5) (p. 31, *infra*), among which are the probable consumption of, or exposure from, the color additive and of any substance formed in foods, drugs or cosmetics on account of its use.

It is entirely clear from the legislative history of 1960 amendments^{*} and from the plain statutory terms that Congress intended to vest in the Commissioner the powers necessary to administer a "safety-in-use" standard for color additives. In adopting a standard which imposed on the Commissioner the burden described by this Court in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 162, of "examination of the effect of the use of colors in the context of" foods, drugs and cosmetics, Congress was surely not disabling the Commissioner from taking the necessary steps to determine whether color additives, *as used in a particular product*, will be safe for their intended use.

The issue which somewhat clouds this case involves the exercise of that necessary power. Finished cosmetic products which impart color to the human body—the subject of one of the challenged regulations in this case—are, beyond any doubt, products which may and often must be examined by the Commissioner to determine, at the very least, how the coloring ingredient contained therein is being used and whether, as used, it will be safe when applied to the lips or on other parts of the human body. Similarly, diluents must often be examined in order to determine whether and to what extent they react with color components. We do not view this case as raising any question of the Commissioner's power to demand that such finished products or diluents be submitted and tested in order to determine whether

^{*} See S. Rep. No. 795, 86th Cong., 1st Sess. (1959); H. Rep. No. 1761, 86th Cong., 2d Sess. (1960).

and under what conditions their coloring ingredient is to be certified and listed as permissible for use. The challenged interpretation of the statute prohibits the sale of any finished color-imparting cosmetic product if that finished product is not itself listed as safe and certified or exempted. We stress this point only to emphasize that the Commissioner's power to require the submission and testing of finished products containing color additives or, indeed, of any other ingredient in a finished product of which a color is a component, does not depend upon whether the regulations here being challenged are valid. The authority to impose these requirements is merely a necessary adjunct of the duty to determine "safety-in-use," and regulations governing such submissions are, therefore, plainly within the scope of Section 701(a)'s authorization to promulgate regulations "for the efficient enforcement" of the Act.

1. Here, as in *Abbott Laboratories*, No. 39, this Term, review at this juncture was impliedly banned by the specific review provisions of the 1938 Act and the 1960 Amendments. The challenged regulations merely interpret provisions of the Act, and Congress did not intend such interpretations to be reviewable prior to their enforcement. Nor does the fact that the agency chose to proceed by formal rule-making under Section 4 of the Administrative Procedure Act subject the interpretive regulations to review at this juncture.

2. Apart from the specific review provisions of the Food, Drug and Cosmetic Act, the controversy is not "ripe" for review because respondents are not pres-

ently subjected to any serious harm as a result of the issuance of the regulations. The Food and Drug Administration plainly has the authority to examine diluents and finished cosmetic products to determine whether their color ingredients are safe for use. Consequently, respondents will not be injured by the regulations until their color ingredients are approved for use and they then attempt to sell them without separate listing or certification.

3. The court below was plainly right in concluding that the challenge to the factory inspection regulation was totally premature. Respondents have adequate remedies to challenge any consequences flowing from failure to allow inspection, if inspection is ever attempted.

ARGUMENT

I

THE CONGRESSES WHICH ENACTED THE FOOD, DRUG AND COSMETIC ACT AND THE COLOR ADDITIVE AMENDMENTS INTENDED TO BAR PRE-ENFORCEMENT JUDICIAL REVIEW OF REGULATIONS SUCH AS THOSE INVOLVED IN THIS CASE

As we have demonstrated in our brief in *Abbott Laboratories*, No. 39, this Term pp. 11-35, Congress, in the review provisions of the Food, Drug, and Cosmetic Act of 1938, struck a compromise. To overcome industry opposition based on a fear of potential administrative usurpation of power in the issuance of regulations having the force and effect of a statute, Congress authorized direct review of such "legislative" regulations in courts of appeals after their adoption but before they became effective (Section

701(f)(1), p. 27, *infra*). On the other hand, to prevent any delay in the enforcement of the remedial provisions of the Act, as they were construed by the administrative agency through the issuance of interpretive regulations, Congress intended to defer review of such interpretations until the regulation had been applied in a specific case. This "highly selective" pattern of review—marked by Congress' specific enumeration of instances when it wished pre-enforcement judicial review and its silence when it did not—was relied on by this Court in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 600–601, which held that the basis for seizures under the Act was not reviewable in advance of an enforcement case.

The Color Additive Amendments of 1960 (adopted by Congress with the gloss of *Mytinger*) manifest a continued adherence by Congress, twenty-two years after the adoption of the 1938 Act, to the original legislative design. The 1960 provisions amended Section 706 to provide that a color additive may not be used unless it receives pre-marketing clearance under regulations to be issued by the Food and Drug Administration pursuant to detailed statutory standards of "safety-in-use" (Section 706(b)). The Food and Drug Administration is directed to list color additives under the conditions under which they may safely be used and to certify batches of additives listed as safe (Sections 706(a)(1), (c), pp. 29, 32, *infra*). No such regulations for cosmetics or cosmetic colors have yet been promulgated, but, when they are, they will plainly be "legislative" in character. They will result from a delegation of power to the administrative agency to

fill the particulars of the statutory scheme which Congress wished implemented. Congress specifically provided for their judicial review before they are to become effective (see Section 706(d), pp. 32-33, *infra*).

The regulations challenged here are different in character. The finished cosmetic, diluent and hair dye regulations are simply administrative interpretations of the Congressional mandate. And it is that legislative direction, not the administrative interpretation, which makes the affirmative demands on the cosmetic industry. In every significant sense, the Food and Drug Administration's construction of the statutory term "color additive" and of the statutory hair-dye exemption is like the National Labor Relations Board's construction of the statutory term "employee," which this Court reviewed in a specific enforcement case in *National Labor Relations Board v. Hearst Publications, Inc.*, 322 U.S. 111. The Food and Drug Administration is authorized to act by rule-making, not adjudication. Hence it cannot announce its understanding of statutory standards, as, for example, can the National Labor Relations Board (see, e.g., *Brooks v. National Labor Relations Board*, 348 U.S. 96; *National Labor Relations Board v. Insurance Agents*, 361 U.S. 477) or the Federal Trade Commission (see, e.g., *Federal Trade Commission v. Mary Carter Paint Co.*, 382 U.S. 46, and authorities cited *id.* at 47, n. 3) in the context of particular cases. Its only alternatives are to proceed informally—a course under which it would not have the benefit of the views of the affected industry or any other form of external detailed scrutiny of its proposed

interpretation—or to issue the statutory interpretation as part of a rule-making proceeding in which interested parties would have an opportunity to present their views. The fact that the agency chose to proceed under Section 4 of the Administrative Procedure Act in this fashion should not subject its interpretation to a challenge which would otherwise be premature under the scheme contemplated by Congress for the enforcement of the Food, Drug and Cosmetic Act. As we have said, review will follow the issuance of specific color additive regulations or when an enforcement case is initiated.

II

THE REGULATIONS ARE NOT RIPE FOR JUDICIAL REVIEW

Here, as in our brief in *Abbott Laboratories*, No. 39, this Term, pp. 35–55, we contend alternatively that the controversy between respondents and the Food and Drug Administration has not yet achieved the degree of certainty and particularity required to make it “ripe” for judicial decision under the Declaratory Judgments Act.

There is little substance to respondents’ assertion that awaiting an enforcement proceeding or following the administrative procedure specifically authorized under the statute would harm them in an immediate and serious fashion. What must be emphasized in this regard is that the critical issue, on this phase of the case, is not whether the regulations, if they are ultimately sustained, require some change in respondents’ manner of doing business, but whether the effect on respondents is likely to be serious or ir-

reparable if they are compelled to resort to ^{the} remedies ~~other than those~~ specifically enumerated. ^{which}

The heart of respondents' claim with respect to the finished cosmetic, diluent and hair-dye regulations is that Congress did not intend to require that they be cleared and listed before being sold or used in any product being sold.⁷ It is plain, however, that except to the extent that provisional listings now permit their sale without certification, the color additive components of these products must be tested, listed and certified as permissible for their intended use prior to any sale of the finished product. On its face, therefore, it is quite apparent that respondents' injury is distant and speculative, for even if color-imparting cosmetics are, as they contend, not "color additives" within the meaning of the statute, no present obligation is imposed upon them. Only when and if the coloring components of the cosmetics are approved, listed and certified for use in those cosmetics or for use with specified diluents will respondents be confronted with practical consequences arising out of the difference of view between themselves and the Food and Drug Administration.

At that juncture the question will be whether respondents must also obtain separate listing and certification or exemption therefrom for their particular finished color-imparting cosmetics before these products may be offered for sale. No substantial injury will be suffered at that stage, we submit, if respondents apply, pursuant to Section 706(b)(2)(A), to have their approved colors and their diluents listed

⁷ We emphasize again (see pp. 8-12, *supra*) that this cannot be read as a challenge to the Secretary's power to examine these products as part of a safety-in-use determination.

in their finished cosmetics on the ground that the color additive ingredients have already been approved for the particular use to which they are put or for combination with the diluents with which they are combined. If, under the interpretation of the statute incorporated in the challenged regulations, the Food and Drug Administration refuses to consider the prior safety-in-use determination as conclusive and requires an independent examination of the finished product, the issue of statutory construction will be squarely presented, in a concrete case, to a court of appeals under the judicial review procedures of Section 706(d), which incorporates Section 701(e), (f), and (g).

Nor, we submit, would there be any real hardship if, in these circumstances, respondents chose to await a condemnation suit.⁸ A proceeding in which the issue would be whether separate listing and certification is required for a color-imparting cosmetic whose color ingredient has been approved, listed and certified for that particular use would be a far more appropriate and concrete way of determining the question which separates respondents and the Food and Drug Administration than the means chosen here.

A condemnation proceeding of the kind described above would be more suitable not merely because it would deal with the controversy at the point in time where it made a practical difference and because it would involve no serious hardship to respondents,⁸

⁸ We do not believe that there is substance to the claim that the seizure authorized by the statute would seriously affect the reputation of the company whose product was seized since it would be quite clear to the public what the basis for the seizure is. And we reaffirm here what we said in our brief in *Abbott*

but also because limiting the remedy in that way would prevent the multiplicity of suits which might otherwise occur. The complaint in this case shows, for example, that the plaintiff corporations reside, for venue purposes under 28 U.S.C. 1391(e)(4), in thirteen different States. If the present action were

Laboratories, No. 39, this Term, p. 41; that where a *bona fide* close question of statutory construction is involved, it is not the policy of the Food and Drug Administration or the Department of Justice to determine that issue in a lawsuit involving severe penalties such as criminal proceedings or multiple seizures.

The alleged excessive cost of separately listing and certifying finished cosmetic products, diluents and the assertedly exempt hair dyes (R. 99-102) is a consideration going to the merits—i.e., to whether the administrative construction of the Act is correct—and not to the issues of ripeness since those costs need not be incurred, in any event, until after the issue is resolved. We also note that the \$2,600 filing charge is not a fee but a deposit to cover processing costs, so that any excess may be returned. 21 C.F.R. 8.50(c). Moreover, there is no requirement that each shade or ingredient of a cosmetic or each diluent be listed separately; a “general use” application with the requisite scientific data may be filed, for example, listing all lipsticks produced by a cosmetic manufacturer (Section 706(b)(2)(A)). It is only where a particular and different product is created with a new use—e.g., “kiss proof” lipstick—involving a different combination of ingredients that a further listing application would have to be filed.

The \$250 fee for listing a diluent (21 C.F.R. 8.50(j)), is not required if the diluent is enumerated in the “general use” petition. Moreover, the Commissioner has prepared a list of certain diluents which will be listed without cost to the cosmetic industry. With regard to “batch certification”, the statute provides authority for exemptions (Section 706(3)) which are specifically carried over into the regulations (21 C.F.R. 8.17). Indeed, it is the present view of the Food and Drug Administration that there will be no requirement for certification of each new batch of listed color cosmetics. At most only periodic or spot-checking certification will be needed.

held permissible, the same reasoning would have to permit thirteen different suits in various district courts throughout the country. No one plaintiff would, of course, be bound by an adverse decision in any other case. The result would be precisely what Congress sought to avoid in enacting the judicial review provisions of the Food, Drug and Cosmetic Act (see our brief in *Abbott Laboratories*, No. 39, pp. 16-17, 21-22, 31-35)—that a single district judge could paralyze the nation-wide administration of the Act.*

III

THE FACTORY INSPECTION REGULATION IS PLAINLY NOT REVIEWABLE AT THIS JUNCTURE

The ruling of the court of appeals that the validity of the factory inspection regulation (21 C.F.R. 8.28 (a) (4), p. 35, *infra*) is not reviewable at the present juncture is, we submit, eminently correct. That regulation authorizes the Commissioner of Food and Drugs to suspend the pre-marketing certification service pro-

* We do not in these cases, as in *Abbott Laboratories*, No. 39, this Term, feel justified in asking this Court to consider the merits if it rejects our view on the ripeness aspect of the decision below. We believe, contrary to the view taken by the district judge (R. 75-76), that the issues of statutory construction can be resolved without evidentiary proceedings and that the record is now adequate to resolve them. But we recognize that the only issues which were certified by the district judge and the court of appeals for interlocutory appeal involved the denial of petitioners' motions to dismiss for want of justiciability and on grounds of sovereign immunity (R. 46-47, 117) and the denial of respondents' motion for summary judgment (R. 118). In these circumstances, we believe the appropriate relief, if the case is justiciable, is to remand for proceedings in the district court.

vided for in Section 706 where "free access" is denied Food and Drug employees to manufacturing facilities, and to processes and formulae relating to the production of color additives and their derivatives. The regulation speaks in permissive terms. The succeeding subsection, (b)(4), provides that, where a suspension notice is served, the party receiving the notice is entitled to a formal hearing as provided in 21 C.F.R. 130.14-130.26, on the "factual basis for the suspension." And it appears that if a "final order" granting suspension is issued by the administrative authority (see 21 C.F.R. 130.26), judicial review of that order is available (see 21 C.F.R. 130.31).

Against this background, there can be little doubt, we submit, that review of this regulation at this stage would be premature. There is nothing to indicate that the Commissioner intends to invoke the factory inspection provision in any particular case as to any party involved in this lawsuit. And even if there were a real probability of his intention to invoke it, this would still pose only a remote threat to a particular cosmetic manufacturer. The "threatened" party would be entitled to a hearing and judicial review before certification could be revoked.

Respondents' complaint fails to demonstrate how the existence of the regulation, *per se*, affects the conduct of its business or in any other way imposes an obligation to do or not to do anything. In these circumstances, we submit, the court below was plainly correct in concluding that "the possibility of unlawful injury to the plaintiffs is, on its face, too remote for declaratory relief" (R. 137).

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals with respect to the First, Second and Third Counts of the complaint should be reversed and its judgment with respect to the Fourth Count should be affirmed. The case should be remanded to the district court with instructions to grant the motion to dismiss the entire complaint for want of justiciability.

Respectfully submitted.

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NOVEMBER 1966.

APPENDIX

The Federal Declaratory Judgments Act, 28 U.S.C. § 2201, provides in pertinent part:

Creation of remedy

In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. * * *

Section 10 of the Administrative Procedure Act, 60 Stat. 243, 5 U.S.C. 1009, now recodified as 5 U.S.C. 701-704 (Public Law 89-554, 80 Stat. 378), provides in pertinent part:

(a) This chapter applies, according to the provisions thereof, except to the extent that—

- (1) statutes preclude judicial review, or
- (2) agency action is committed to agency discretion by law.

* * * * *

§ 702. RIGHT OF REVIEW

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.

§ 703. FORM AND VENUE OF PROCEEDING

The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action,

including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

§ 704. ACTIONS REVIEWABLE

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, or an appeal to superior agency authority.

The Federal Food, Drug and Cosmetic Act, as amended, provides, in pertinent part:

Section 201(t)(1), 21 U.S.C. 321(t)(1):

The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

Section 361, 21 U.S.C. 361, provides in pertinent part:

Adulterated cosmetics

A cosmetic shall be deemed to be adulterated—

(a) bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: 'Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness', and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this subsection and subsection (e) of this section the term 'hair dye' shall not include eyelash dyes or eyebrow dyes.

* * * * *

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).

Section 701, 21 U.S.C. 371, provides in pertinent part:

(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

* * * * *

(e)(1) Any action for the issuance, amendment or repeal of any regulation under section 401, 403(j), 404(a), 406 (a) or (b), 501(b), or 502 (d) or (h), 504 or 514 of this act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds the emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f)(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of Title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such addi-

tional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order; or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 346 and 347 of Title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

* * * * *

Section 706, 21 U.S.C. § 376, provides in pertinent part:

(a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), 501(a)(4), or 601(e) of this Act, as the case may be, unless—

(1) (A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c) of this section, for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) of this section with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) of this title if such article is a food, or within the meaning of section 601(a) of this Act if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a) of this Act).

(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities, which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the

regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s) of this Act.

(5)(A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) of this section and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided, That*, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

(d) The provisions of section 701 (e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection (b)(5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such nine-

tieth day) by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b)(5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409(f)(2); and

(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

(f) The Secretary shall by regulations (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

Section 704, 21 U.S.C. 374, provides:

(a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any

such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of this Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or

process drugs solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

* (b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or

packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food; a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

21 C.F.R. 8.1(f) provides in pertinent part:

A "color additive" is any material, not exempted under section 201(t) of the act * * *. This includes all diluents. * * * A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants, Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." * * *

21 C.F.R. 8.1(m) provides:

The term "diluent" means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

21 C.F.R. 8.1(u) provides:

The "hair dye" exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes

or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious substance in the "hair dye" is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.

21 C.F.R. 8.28(a)(4) provides:

(a) When it appears to the Commissioner that a person has:

* * * * *

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived; he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

21 C.F.R. 8.28(b) provides:

Upon receipt of the notice of suspension of service, the person so notified may request a hearing upon the factual basis for the suspension. The procedure at the hearing shall conform as nearly as possible to the procedure described in §§ 130.14-130.26 of this chapter.

Nos. 336, 438

DEC 30 1966

JOHN F. DAVIS, CLERK

Supreme Court of the United States

OCTOBER TERM, 1966

THE TOILET GOODS ASSOCIATION, INC., ET AL., *Petitioners,*

v.

**JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, and JAMES L. GODDARD, COMMISSIONER
OF FOOD AND DRUGS,** *Respondents.*

**JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, and JAMES L. GODDARD, COMMISSIONER
OF FOOD AND DRUGS,** *Petitioners,*

v.

THE TOILET GOODS ASSOCIATION, ET AL., *Respondents.*

**ON WRITS OF HABEAS CORPUS TO THE UNITED STATES COURT OF
APPEALS FOR THE SECOND CIRCUIT**

**BRIEF FOR PETITIONERS IN NO. 336 AND FOR
RESPONDENTS IN NO. 438**

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H. Rep. 2755, 74th Cong., 2d Sess. (1936), p. 8.....	45fn
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"Final Report of the Attorney General's Committee on Administrative Procedure" (1941).....	33, 34
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Paper by William W. Goodrich, Asst. General Counsel, FDA, published in The Business Lawyer, Vol. XVIII, No. 1, Nov. 1962, pp. 203, 204, 207....	19, 19fn, 20, 20fn

Supreme Court of the United States

OCTOBER TERM, 1966

No. 336

THE TOILET GOODS ASSOCIATION, INC., ET AL., *Petitioners,*

v.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS, *Respondents.*

No. 438

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS, *Petitioners,*

v.

THE TOILET GOODS ASSOCIATION, ET AL., *Respondents.*

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR PETITIONERS IN NO. 336 AND FOR RESPONDENTS IN NO. 438

Question Presented.

Whether members of an industry* affected by final agency regulations can challenge their validity in equity for an injunction and under the Declaratory Judgments and Administrative Procedure Acts, where:

* The complaint is by 39 companies which manufacture cosmetics and their trade association, whose members represent over 90% of industry sales (R. 2-5).

(a) The regulations are challenged as in excess of the agency's statutory authority, and their validity turns on questions of statutory construction which do not involve agency expertise;

(b) The regulations impose new requirements which necessitate drastic alteration of business practices involving substantial expense and irrevocable harm, and have an immediate and substantial impact on the industry, including exposure of valuable trade secrets;

(c) The challenge is against four provisions inter-related as elements of a common plan of agency regulation;

(d) Non-compliance with any of such four provisions could cause the product affected to be banned from the market and, if thereafter sold, entail civil and criminal prosecution, seizure proceedings and harmful administrative actions; and

(e) The power and authority assumed by the agency in the regulations are substantially the same power and authority sought in agency sponsored legislation, but which Congress withheld.

Statutes and Regulations Involved.

This case involves the Declaratory Judgments Act (§274D, Jud. Code (1934), 28 U.S.C. §§2201-02); the Administrative Procedure Act (60 Stat. 243 (1946), 5 U.S.C. §551, *et seq.*); the Federal Food, Drug and Cosmetic Act (52 Stat. 1040 (1938)), as amended by the Color Additive Amendments of 1960 (74 Stat. 397 (1960), 21 U.S.C. §§321(t)(1), 361, 371, 374, 376); and the Color Additives Regulations (28 Fed. Reg. 6439 (June 22, 1963), 21 C.F.R. 8.1 *et seq.*, §§8.1(f)(m)(u), 8.4, 8.26, 8.28, 8.30(a), 8.50 and 8.51(a)). The relevant portions not included in petitioners'* Appendix are in the Appendix to this brief.

* Consistent with the Government's brief (Br. 4, fn. 3), the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs, petitioners in No. 438 and respondents in

Statement.

Introduction.

The case involves the validity of four provisions of regulations issued June 22, 1963 by the Commissioner of Food and Drugs ("FDA"), entitled "Color Additives" (the "Regulations") (28 Fed. Reg. 6439, 21 C. F. R. 8.1 *et seq.*). The Regulations were promulgated under the "Color Additive Amendments of 1960" (74 Stat. 397, 21 U. S. C. §321) (the "Amendments"), which amended the Federal Food, Drug, and Cosmetic Act (the "Act").

The Amendments require FDA listing of "color additives" "for use in or on" food, drugs and cosmetics "if and to the extent that such additives are suitable and safe for any such use" (§706(b)(1) of the Act),* and subsequent certification "of batches of color additives" which have been listed, unless exempted from certification (§706(c)). Color additives so used and not listed and certified are "deemed unsafe" (§706(a)). Food, drug and cosmetic products which contain color additives thus "deemed unsafe" are "deemed to be adulterated" (§§402(c), 501(a)(4)(A), 601(e)), and their sale entails drastic criminal and civil penalties, including multiple seizures (§§301(a), 302, 303, 304).

The four provisions of the Regulations involved in this case, each of which is the subject of a separate count in the complaint, accomplish the following:

- (1) Require listing, after prescribed tests, and certification, of all finished cosmetic products which impart

No. 336, are herein referred to as "petitioners"; respondents in No. 438 and petitioners in No. 336 are herein referred to as "respondents."

* Consistent with the Government's brief, references to sections of the statute will be to the Act rather than to the Code.

a color to the body, such as lipstick, rouge and eye make-up colors, whereas the Amendments require listing and certification only of the color ingredient added to the product;

(2) Apply such listing and certification requirements to non-color ingredients of finished cosmetic products, which the Regulations call "diluent", whereas the Amendments make no provision for listing diluents and merely authorize certification of the color ingredient, with safe diluents or without diluents;

(3) Change and limit the statutory exemption for hair dye products, in addition to applying such listing and certification requirements to such products, whereas the Amendments do not affect the exemption for such products; and

(4) Grant FDA inspectors access to cosmetic formulae, a subject not even mentioned in the Amendments.

Proceedings Below.

Respondents sued in the United States District Court for the Southern District of New York for a declaratory judgment that each of such four provisions of the Regulations are invalid as in excess of petitioners' statutory authority, and for an injunction against enforcement.*

Petitioners moved to dismiss on numerous technical and procedural grounds, principally for failure "to state a case of actual controversy * * * because of the absence of any threatened or attempted enforcement of the regulations" (R. 69). Respondents moved for summary judgment.

The District Court found "compelling reasons for assuming jurisdiction and determining in this action the validity of the challenged regulations" (R. 73), but denied

* Jurisdiction was invoked under 28 U.S.C. §1331(a), and the action was alleged to be authorized by the Declaratory Judgments Act, 28 U.S.C. §§2201, 2202 and Section 10 of the Administrative Procedure Act, 5 U.S.C. §1009, later recodified as 5 U.S.C. §§701-706 (R. 7).

summary judgment, concluding that "testimony relative to legislative intent" was desirable (R. 75).

After extensive discovery, petitioners made a renewed motion to dismiss based on *Abbott Laboratories v. Celebrezze*, 352 F. 2d 286 (3d Cir. 1965), cert. granted, 383 U. S. 924 (1966), No. 39, and *The Danville Tobacco Association v. Freeman*, 351 F. 2d 832 (D. C. Cir. 1965), "on the grounds that (a) the complaint fails to set forth a justiciable controversy and (b) this is an unconsented suit against the United States" (R. 76). The District Court, finding the situation "significantly different" from *Abbott Laboratories* (R. 50), denied the motion. The case was certified for interlocutory appeal and appeal was allowed (R. 52, 117).

The Court of Appeals, though finding *Abbott Laboratories* "not distinguishable on any satisfying basis" (R. 135), held that the issues framed as to the three provisions involved in the first three counts of the complaint,—which, as above noted, extended the Amendments' listing and certification requirements from color ingredients to the finished product itself, including hair dyes, and to its non-color ingredients,—were "suitable for immediate judicial resolution" (R. 136). However, as to the fourth count,—relating to access to cosmetic formulae,—the Court of Appeals concluded that injury to respondents was "too remote for declaratory relief" (R. 137), and reversed.*

Since it was assumed the identical test of reviewability applied to all four challenged provisions of the Regulations, they were always considered collectively below. The Court of Appeals, without the issue having been briefed or argued, made the distinction as to the fourth count,—the issued presented by No. 336.

* The Government's claim that this is an uncontested suit against the United States was rejected as "plainly foreclosed by Supreme Court decisions" (R. 129, fn. 6) and has been abandoned.

Background of the Regulations.

To make it appear the challenged provisions of the Regulations impose "no present obligation" on the cosmetic industry, that "respondents' injury is distant and speculative" (Br. 17) and that the case merely presents differences of "interpretation" or legal opinion, petitioners present a beclouded description of the Regulations and their impact. A fair description of the Regulations is prerequisite to the issue of judicial reviewability. Also essential to full understanding is an analysis of the statutory scheme and the background and legislative history of the Amendments, as well as a description of their provisions.

These will show that the Regulations apply forthwith and have a direct and immediate impact on the cosmetic industry, and that the issue is not one of mere "interpretation" but of administrative usurpation of power and authority beyond and radically different from that granted by the Amendments. While this is apparent by merely comparing the Regulations with the Amendments, perhaps aided by their legislative history, it is buttressed by the fact that each challenged power FDA took by the Regulations had been sought from Congress and withheld.

The Statutory Scheme.

The Act,—which imposes severe civil and criminal penalties for sale of "adulterated" articles of food, drugs and cosmetics,—places finished products and their ingredients in three carefully delineated categories:

(1) The first is *finished products* [food, drugs (other than "new drugs,") and *cosmetics*], which do not require prior FDA approval or premarketing clearance, but as to which after sale the manufacturer and seller, and the product itself, are subject to penalties if the product is "deemed to be adulterated", that is, "contains any poisonous or

deleterious substance which may render it injurious to users" (§601 (a)). Except as to "new drugs", finished products need not be cleared before marketing. Congress, however, specifically exempted from coverage, *even after sale*, hair dyes (other than eye-lash or eyebrow dyes), if labelled as required by the Act (§601 (a)).

(2) The second is a "*new drug*", the only finished product which requires prior FDA approval or premarketing clearance (§505 (a)).

(3) The third is *specific ingredients* in the product. As to food, prior clearance is required for various added ingredients called "food additives";—a requirement imposed by the "Food Additives Amendment of 1958" (72 Stat. 1784 (§409)).

As to food, drugs and cosmetics, prior FDA clearance, as noted above, is also required for the color ingredient added to the product and called a "color additive". Such prior clearance is accomplished by requiring (i) pretesting of the color to establish safety; (ii) petitioning FDA for listing the color in a regulation, which states the specifications for the color; and (iii) FDA certification of batches of the color to establish compliance with its specifications (§706 (b)(c)), unless the color is exempted from certification.

The exemption for finished hair dye products was also implemented in Section 601(e) to exempt the color ingredient in the hair dye.

The Act grants FDA certain factory inspection authority. FDA agents may inspect "processes" of prescription drugs only, not cosmetics, food and non-prescription drugs (§704(a)).

Background of the Color Additive Amendments.

(1) The Act Prior to the Amendments.

A color ingredient is added to food, drugs and cosmetics, either to impart color to the product or to enable the product to apply color to the body. The color ingredient may be a dye, pigment or some other substance (R. 7-8, 103). The term "color additive" signifies that the color ingredient has been added to the product (R. 7).

Color additives may be colors derived from natural sources, known as "natural colors", or be made by a process of synthesis, known as "synthetic colors". Synthetic colors became generally used as the color additive in food, drugs and cosmetics, particularly chemical compounds of a coal-tar origin known as "coal-tar colors" (R. 8, 103).

Under the 1938 Federal Food, Drug and Cosmetic Act (52 Stat. 1040),—the first to regulate cosmetics,—only coal-tar colors were required to be listed and certified* (R. 9-10).

FDA regulations defined coal-tar colors and prescribed the requirements for listing, involving pretesting and scientific investigations, and for certification of batches of coal-tar colors. FDA regulations listed a total of 118 coal-tar colors, with specifications for the color. (21 C.F.R. (1949 ed.) §135, pp. 113-128.) There was never a listing of the finished cosmetic product itself or its numerous non-color ingredients. Nor was there ever listing of a hair dye product or its color ingredient, or disclosure of the formula of a cosmetic product (R. 105-6).

*"SEC. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents."

Comparable provisions of the 1938 Act applied to food (§§402 (c), 406(b)) and drugs (§§501(a)(4), 504).

(2) **Emergency Which Resulted in Enactment of the Color Additive Amendments as a Relief Measure for the Color, Food, Drug and Cosmetic Industries—The “Harmless *per se*” Principle *versus* the “Safe-for-Use” Principle.**

In 1952, FDA determined that the statutory provisions “for the listing of coal-tar colors which are *harmless and suitable for use*”^{*} in food, drugs and cosmetics meant the color had to be entirely lacking in toxicity; that “harmless” was used in an absolute sense; that if a coal-tar color in any quantity, regardless of how large or concentrated, could produce any toxicity, it could not be listed as “harmless and suitable for use” even if harmless as to a particular use in a food, drug or cosmetic, or in the tolerance or quantities involved in such use; and that FDA could not establish tolerances for the use of coal-tar colors in the finished product. This is called the “harmless *per se* principle” (R. 10-11).

Prior to 1952 and since 1906, the applicable test was whether the color was harmless in the actual quantity used or in its particular use or application. This is called the “safe-for-use” principle (R. 11).

Application of the “harmless *per se*” principle was sustained in *Flemming v. Florida Citrus Exchange*, 358 U. S. 153 (1958). As a consequence, substantially all coal-tar colors had to be delisted, threatening removal from the market of articles of food, drugs and cosmetics which contained such colors, which had received wide consumer acceptance and which experience had established were safe in their particular uses. Remedial legislation was urgently needed to sanction the “safe-for-use” principle and prevent needless destruction of the color, food, drug and cosmetic industries (R. 10-11, 111-2).

^{*} Unless otherwise noted, italics throughout have been supplied.

Accordingly, FDA, in close association with the affected industries, prepared the bill which became the Color Additive Amendments of 1960 (R. 11).

(3) The Legislative History of the Color Additive Amendments—Their Two-fold Purpose.

The Amendments' primary purpose was to counteract *Flemming v. Florida Citrus Exchange* and enable FDA to establish quantity or tolerance limitations for colors in particular products. FDA decided also to obtain extension of listing and certification from coal-tar colors alone to all colors, natural and synthetic. This two-fold purpose is clear from the legislative history.

It was stated in the House Report on the Amendments, which summarized the "principal reasons which give rise to the need for this legislation" (R. 109-113, 12):

"1. The law with respect to coal-tar colors * * * does not allow the Secretary of Health, Education, and Welfare to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. * * * the Secretary must ban the use of such a color completely, as not being 'harmless,' if it is found to be toxic in the laboratory when fed to animals in some concentrations, even though its actual level and manner of use may be completely safe."

* * * * *

"3. There is a need for making applicable to all color uses and all types of color—whether they be coal-tar colors or others—the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirements for certification of colors to assure their purity and identity with those listed as safe."

* * * * *

"The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of *colors* under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, * * *"

There is not a suggestion in the entire legislative history* of any intent to extend pretesting, listing and certification from color ingredients alone to finished cosmetic products, and thereby establish an entirely new system of premarketing clearance for such products or their non-color ingredients; or to eliminate, limit or modify the statutory exemption for hair dye products; or to grant FDA access to formulae of cosmetics. Clearly, such major innovations would have been noted during the protracted legislative history. *Ozawa v. United States*, 260 U. S. 178, 194 (1922).

On the contrary, it was emphasized that the Bill did not require premarketing clearance; a strong recommendation that such requirement again be considered was not adopted.**

* See "Color Additives, Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives", 86th Cong., 2 Sess., on H. R. 7624 and S. 2197, pp. 15-6 ("1960 Hearings"). The twofold purpose was also emphasized in testimony before the Committee (pp. 39-40), in statements by Committee members (pp. 1-2) and in discussion in the House (106 Cong. Rec. 14349, 14350, June 25, 1960).

** Congresswoman Sullivan, who had sponsored legislation for premarketing clearance of cosmetics, stated that such "cosmetic bills have been pending before you for some years," that the color additives bill would "establish, for the first time, a basis for clearing in advance the safety of non-coal-tar colors used in cosmetics," and further stated:

"But what of all of the other ingredients in cosmetics? If we are going to require manufacturers to prove the safety

The Provisions of the Color Additive Amendments.

The Amendments accomplished the two-fold purpose in the following manner:

(1) The requirement for listing and certification was extended from coal-tar colors to all colors by changing "coal-tar color", used in the 1938 Act, to "color additive". The term "color additive", to designate color ingredients added to food, drugs and cosmetics, evolved from "food additive" adopted in the 1958 Amendments to designate ingredients added to food (R. 112). As already noted, FDA had defined coal-tar color by regulation. This definition was carried into the Act, except that "coal-tar color" was changed to "color additive" and appropriate language was used to cover the natural colors. (R. 103, 14). (§201(t), App. Pet. Br. 24-5).

(2) The second purpose, authorizing FDA to list colors on the basis of quantity limitation and a specific product, was covered by Section 706(b) entitled "Listing of Colors", which authorized "tolerance limitations, as to the maximum quantity or quantities which may be used", and other conditions of use of the color added to the food, drug or cosmetic.

The Amendments did not change the statutory exemptions for hair dye products (§601(a))* or affect or even mention factory inspection.

of their non-coal-tar color additives in cosmetics, why not in the same legislation and at the same time and under the same standards require the manufacturer to establish the safety of all ingredients in his cosmetics product?" (1960 Hearings, pp. 1134.)

* The actual amendments, prior to collation into the Act, underscored Congressional intent not to affect the hair dye exemption, by describing Section 601(e) as "relating to cosmetics, other than hair dyes". (P. L. 86-618, 74 Stat. 397, 398, §102(c) (1)). The House Report explained that the Amendments contained such hair dye exception "since coal-tar hair dyes are not covered by section 601(e) of the act" (H. Rpt. No. 1761, dated June 7, 1960, U. S. Code, Cong. Adm. News (1960), Vol. 2, p. 2906).

The Provisions of the Color Additives Regulations.

The Regulations accomplish the purpose of the Amendments by prescribing the procedure for listing all colors, coal-tar and natural, and for certification or exemption from certification, and by covering the tests "applicable to show whether or not the color additive will be safe for its intended use" in the article of food, drug or cosmetic, including such matters as "proposed tolerances" (§8.4(c), App. pp. 2a-3a, *infra*). However, the Regulations far exceed both the language and purpose of the Amendments in four areas. As to each area FDA had sought legislation to obtain the desired power, but Congress refrained from the grant. Finally, FDA just took the power, as follows:

(1) FDA's Assumption of Power to Require Premarketing Clearance of Finished Cosmetic Products.

FDA, in defining "color additives" in the Regulations, inserted one brief sentence which subjects substantially the entire cosmetic industry to premarketing clearance of finished cosmetic products (§8.1(f), App. Pet. Br. 37):

"Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives'."

FDA's release of June 22, 1963, announcing the Regulations, described them as imposing a "new requirement" and stated (R. 106):

"Under the new regulations, FDA will require that an entire product—not just the color ingredient—be shown by the manufacturer to be safe before it is released for sale."

Petitioners acknowledge that the Regulations apply the listing and certification requirements not only to the color ingredient but also to the finished cosmetic product, and that "the sale of any finished color-imparting cosmetic product [is prohibited] *if that finished product is not itself listed as safe and certified or exempted*" (Br. 12).

FDA, to minimize the Regulations' scope, asserts FDA "does not require pre-marketing licensing" "for cosmetics which do not impart color to the human body" (Br. 5, fn. 4). However, it is conceded the Regulations impose pre-marketing clearance for lipstick, rouge, eye makeup colors, all hair dyes and hair coloring products, leg applications, pancake makeup, suntan lotions, nail polish and nail enamel and innumerable other cosmetics. Since "color" is defined to include "white" (§8.1(f)), FDA agreed the regulations even embrace shaving creams, baby oils and like products. Ellenbogen of FDA was unable to specify any cosmetic not covered by the Regulations; he did not "know of any", could not "name any offhand", and was "not sure" whether all toothpastes were covered (R. 88-89).*

However, regardless of whether certain cosmetics are reached, it suffices as to the issue of excess of statutory authority that the Regulations impose premarketing clearance for the cosmetics above mentioned, which are manufactured by respondents whose businesses are drastically affected thereby.

* Petitioners err in stating there is dispute as to the Regulations' coverage and that respondents have claimed they "establish a pre-marketing licensing system for *all* cosmetic products and ingredients," whereas FDA claims the Regulations apply "only to those cosmetics that impart color to the human body" (Br. 5, fn. 4). Petitioners have never claimed the Regulations specifically apply to "all cosmetic products." The complaint recognizes they apply only to "cosmetics intended for applying color to the human body" (R. 20, 42). Petitioners have merely shown that by defining color to include white, the reach of the Regulations became extremely extensive. This is confirmed by FDA's difficulty in specifying cosmetics not covered by the Regulations.

(2) FDA's Assumption of Power to Require Premarketing Clearance of Non-Color Cosmetic Ingredients.

The Regulations catch substantially all non-color cosmetic ingredients by providing that "color additive" "includes all diluents" (§8.1(f)), defined to mean substantially all non-color cosmetic ingredients (§8.1(m), App. Pet. Br. 37).

A diluent is an inert substance used to dilute dyes or pigments, which are generally stronger than needed to impart color to the product (R. 104-5). The term "diluent", as already noted (p. 8, fn., *supra*), was used in the 1938 Act when its listing and certification requirements concededly applied only to coal-tar colors. There was no requirement for listing diluents; the Act merely provided that a coal-tar color in food, drugs or cosmetics could be certified "with or without harmless diluents" (§604; see p. 8, fn., *supra*). This pattern was preserved by the Amendments which nowhere suggest diluents must be listed, but merely authorize color additives to be *certified* for use "in or on food or drugs or cosmetics" "with safe diluents, or without diluents" (§706(a)(c)).

Since the primary purpose of the non-color ingredients is not to dilute the color, but to serve as emollients, stabilizing, emulsifying, imparting an odor, and the like, they are not, and have never been considered, diluents. Neither listing nor certification of such non-color ingredients was ever required (R. 104, 28-9).

The Amendments made no change as to diluents. The legislative history nowhere suggests that non-color ingredients be deemed diluents or that diluents be listed.

By defining "color additive" to include "all diluents," and defining "diluents" to mean substantially all non-color cosmetic ingredients, FDA has assumed the power to require pretesting, *listing* and certification of substantially

all ingredients in all cosmetics (R. 28-9). Miller of FDA conceded the Regulations define "diluent" "to include every ingredient of every cosmetic product that contains a color" (R. 85).

(3) FDA's Repeal and Limitation of the Statutory Hair Dye Exemption.

The Regulations substantially repeal the statutory hair dye exemption in two ways:

(i) The definition of color additive, embracing any cosmetic "intended for coloring the human body" (§8.1(f)), includes all hair dye products, and thereby requires for them the same premarketing clearance imposed for lipstick, rouge and the like.

(ii) The Regulations seek to repeal the statutory exemption for hair dye products and their color ingredients (§8.1(u), App. Pet. Br. 37-8).

FDA's intent to rewrite the Act is manifest from its release of June 22, 1963, which stated that the statutory hair dye exemption offered insufficient protection; that "the purpose of the new regulation is to close this gap", and that hair dyes which do not cause a reaction with the prescribed test for skin sensitivity "*must now be demonstrated to be safe before they can be marketed*" (R. 106).

Equally candid is the FDA release of October 3, 1963, which describes the Regulations as "*limiting* the exemption for hair dyes under the Federal Food, Drug, and Cosmetic Act" (R. 108).

FDA cannot even purport to justify repealing or limiting the hair dye exemption by anything in the Amendments, which, as already noted, did not even touch the Act's hair dye provisions, except to reaffirm the statutory exemption.

Substantially the entire cosmetic industry in the United States is presently subject to the Act's criminal and civil sanctions, including multiple seizure of substantially all its products, for non-compliance with the first three challenged provisions of the Regulations. FDA has indicated it would defer criminal and civil enforcement proceedings during pendency of this action (R. 90).

(4) FDA's Assumption of Power to Require "Free Access" to the Processes and Formulae of Cosmetics.

The Regulations in effect grant FDA access to cosmetic processes and formulae by providing for suspension of certification for refusal of "free access to all manufacturing facilities, *processes*, and *formulae* involved in the manufacture of color additives" (§8.28(a), App. Pet. Br. 38), defined to include substantially all finished cosmetic products. Suspension of certification prevents sale of the product and will, as the accompanying FDA release stated, "in effect ban it from the market" (R. 106-7).

Here, also, FDA cannot justify extension of statutory inspection power by anything in the Amendments, which did not touch the factory inspection provisions.

Since reviewability of the "free access" provision is a separate issue presented by No. 336, the background of such provision and the manner whereby FDA took power long desired by it, and long withheld by Congress, will be separately developed (pp. 18-21, *infra*).

Congressional Refusal to Grant FDA the Power Taken by the Color Additives Regulations.

(1) The First Three Challenged Provisions of the Regulations, Reviewability of Which Is Presented By No. 438.

Pertinent to FDA's excesses of statutory authority is the fact, already alluded to, that FDA itself sponsored

legislation to obtain the very powers taken by the Regulations. The bills were numerous.*

One example, H. R. 11582, introduced May 3, 1962, should suffice (R. 114-5). Title I, entitled "PREMARKETING CLEARANCE OF COSMETICS FOR SAFETY," contains provisions limited to "New Cosmetics" which parallel the provisions for approval of "new drugs." They require a "new cosmetic" application, accompanied by "full reports of investigations" "to show whether or not such cosmetic is safe for use", and "a full statement of the composition of such cosmetic" (§605(b)(1)(3)). A cosmetic is "deemed unsafe" and therefore may not be sold unless the application has been approved (§605(a)).

Section 103, entitled "REPEAL OF SPECIAL EXEMPTIONS FOR HAIR DYES," contains provisions deleting the Act's hair dye exemption (R. 116).

Comparable legislation was sought the following year, including another FDA sponsored bill.**

(2) The "Free Access" Provision of the Regulations, Reviewability of Which is Presented By No. 336.

The Act's original factory inspection provision authorized FDA, after "obtaining permission of the owner," to enter factories manufacturing food, drugs, devices and cosmetics and inspect "all pertinent equipment, finished and unfinished materials, containers, and labeling therein" (52 Stat. 1057, §704). The right to inspect processes and formulae was not granted.

* Three such bills are annexed as exhibits to an affidavit in behalf of respondents (R. 88). In preparing the Appendix for the Court of Appeals, petitioners failed to reproduce these exhibits, and hence they are not included in the printed record before this Court.

** H. R. 1235, introduced January 9, 1963, 88th Cong., 1st Sess., and H. R. 6788, introduced June 4, 1963, 88th Cong., 1st Sess.

In 1953, following *United States v. Cardiff*, 344 U. S. 174 (1952), the Act was amended to eliminate the permission requirement (67 Stat. 477). But inspection of processes and formulae was still not granted. According to William W. Goodrich, counsel for petitioners in both Nos. 336 and 438:

"The managers of the bill expressed their opinions that it would not be a reasonable inspection to demand access to formula files * * *."

FDA subsequently sponsored the "Drug and Factory Inspection Amendments of 1962" (H. R. 11581, 87th Cong., 2d Sess.), whereby it sought access to factories "in which food, drugs, devices, or cosmetics are manufactured," and to inspect "all things therein (including * * * processes * * *)". The stated purpose was to "strengthen existing inspection authority" to grant FDA access to "processes" of food, drugs, devices and cosmetics**.

The Secretary testified that FDA inspectors "are refused access to formula files" and that (1962 Hearings, pp. 67, 68):

"H. R. 11581 would remedy this problem by granting the Food and Drug Administration authority to make complete inspection of all establishments producing foods, drugs, devices; or cosmetics. This

* Paper delivered by William W. Goodrich, Assistant General Counsel, FDA, before American Bar Association's Food, Drug & Cosmetic Law Division, Aug. 8, 1962, published in *The Business Lawyer*, Vol. XVIII, No. 1, Nov. 1962; pp. 203, 204.

** Drug Industry Act of 1962, Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 87th Cong., 2d Sess., held June 19, 20, 21, 22; Aug. 20, 21, 22, 23, 1962 on H. R. 11581 and H. R. 11582 (the "1962 Hearings"), pp. 11, 30.

provision would allow inspection of all . . . processes,”

He further testified as to his existing authority (1962 Hearings, p. 72):

“The Chairman: Are you authorized to look at the formula files?

“Secretary Ribicoff: We are not.”

Industry opposition came not only from the cosmetic industry but from the food industry, which was most concerned at the threatened exposure of vital trade secrets.*

Congress enacted the requested “free access” to processes and formulae, but only as to factories “in which prescription drugs are manufactured” (§704 (a), 76 Stat. 792). It withheld the authority as to foods, non-prescription drugs, devices and cosmetics. The law, as passed October 10, 1962, dropped “Factory Inspection” from its title, and was called “Drug Amendments of 1962”.**

To underscore the Amendments’ inapplicability to cosmetics, Congress specifically provided they “shall not apply to any cosmetic unless such cosmetic is also a drug or device or component thereof.” (§509, 76 Stat. 791)

FDA Counsel Goodrich stated that the “need” for FDA access to formulae of all products was so “real” that “we will continue with all our abilities to urge the Congress to meet the need.”***

Accordingly, in 1963 FDA sponsored H. R. 6788,† Section 101 of which was captioned “EXTENSION OF PRESCRIP-

* See particularly a statement by the National Canners Association (1962 Hearings, p. 137).

** §704(a), as amended by Pub. L. 87-781, Oct. 10, 1962, 76 Stat. 792, §201. These amendments and certain regulations thereunder as to labeling are the ones involved in *Abbott Laboratories v. Celebrezze* (No. 39).

*** Business Lawyer, Vol. XVIII, Nov. 1962, p. 207.

† See p. 18 fn., *supra*.

TION DRUG INSPECTION AUTHORITY TO OTHER DRUGS, FOOD, COSMETICS, AND DEVICES". The Secretary's transmittal letter, dated May 29, 1963, stated that "The enclosed bill would * * * extend the inspection authority presently applicable only to prescription drugs to all other products covered by the Food, Drug, and Cosmetic Act." The requested authority was again withheld.

Subsequently, FDA, by the challenged regulation, simply took the power to obtain "free access" to all cosmetic "processes, and formulae." Its accompanying release warned that refusal of such access "*may*" cause FDA to refuse to certify the cosmetic and "*thus in effect ban it from the market*" (R. 106-7). FDA use of "*may*" rather than "*will*", which so strongly influenced the Court of Appeals to regard the possibility of unlawful injury as too remote for declaratory relief (R. 137), can hardly soften the impact on the cosmetic industry of the power it illegally took or its warning to industry.

The Finality and Mandatory Nature of the Regulations.

The District Court determined the Regulations are "final" (R. 49, 50). Below petitioners also called them "final regulations" (Br. CA, p. 8), though they now suggest lack of finality (Br..17).

The Regulations were promulgated pursuant to the "Rule making" procedure of the Administrative Procedure Act (the "APA"), 5 U. S. C. §553. FDA first gave "General notice of proposed rule making * * * published in the Federal Register" January 24, 1961* (26 Fed. Reg. 679) (§553(b)). It afforded "interested persons opportunity to participate in the rule making through submission of written data"* (§553(c)) and published the final

* Petitioners advance the lame excuse,—not suggested until this Court,—that they followed APA's formal rule making pro-

Regulations June 22, 1963 (28 Fed. Reg. 6439, 21 C. F. R. §§8.1 *et seq.*). Accordingly, "The process of rulemaking was complete. It was final agency action" and the Regulations "now operate to control the business affairs" of respondents. (*United States v. Storer Broadcasting Co.*, 351 U. S. 192, 198, 199 (1956)).

The Regulations state that "This order shall become effective" on publication in the Federal Register, except that "§8.30 [as to certain diluents] shall become effective one year after publication."

An FDA release stated its "regulation limiting the exemption for hair dyes * * * applies immediately only to new hair dye formulations coming on the market * * *. Products currently being marketed *will not be affected* until June 22, 1965 * * *" (R. 108).

A mere "difference of view" or announcement of what FDA "believes," as petitioners characterize the Regulations (Br. 17, 8), would not be called an order, or provide for an effective date or have three separate effective dates. This alone shows the Regulations are meant to have the force of law. (*Cf. Columbia Broadcasting System, Inc. v. United States*, 316 U. S. 407, 420-421 (1942).)

FDA stressed their mandatory nature. Its formal release, describing the applicable provision as a "new require-

cedure because otherwise "it would not have the benefit of the views of the affected industry" (Br. 15). This argument is patently specious. It is common practice for FDA informally to obtain industry comments on any proposed action, and this could be done without the formal rule making procedure.

Furthermore, the notice of the proposed rule making did not even contain the challenged provision defining "color additives" to include lipstick, rouge and other finished cosmetic products so that industry was not even apprised of FDA's intent to require the listing and certification of finished cosmetic products or to obtain access to cosmetic formulae.

ment," stated that before the Regulations "only color . . . ingredients had been subject to the requirement for premarketing proof of safety," whereas now "FDA *will require*" premarketing clearance for the "entire [cosmetic] product—not just the color ingredient" (R. 106). Referring to an alleged loophole in the Act as to hair dyes,—the FDA release stated the Regulations "close the gap" and hair dye products "*must* now be demonstrated to be safe before they can be marketed" (R. 106).

FDA's answers to interrogatories state: "Any cosmetic intended to impart color to the human body *would have to be listed*" (R. 83). Deputy FDA Commissioner Harvey agreed the Regulations "*require* listing" of substantially all cosmetics (R. 83). This hardly suggests the Regulations impose "no present obligation" (Br. 17).

The Burdens Imposed on the Cosmetic Industry by the Regulations.

The Regulations, to the extent they exceed the statutory authority, have direct and immediate impact on respondents, impose tremendous burdens not authorized by the statute and cause respondents irreparable harm (R. 21-2, 29-30, 37, 41, 99-102).

(1) The Regulations require a separate petition for listing every cosmetic which imparts color to the body, as well as their non-color ingredients (§§8.1(f)(m), 8.4(c)). For respondent Kolmar Laboratories, Inc. ("Kolmar") alone,—a private brand manufacturer which makes over 2,700 different formulae and cosmetics which color the body,—the listing fees, at \$2,600 a cosmetic (§8.50(c)), would be approximately \$7,000,000. Since Kolmar uses 264 non-color ingredients in its finished cosmetic products, which the Regulations now call "dilutents", it must now

also obtain separate listing* for such ingredients (§8.50(j)) (R. 99-100, 22).

(2) Each listing petition must be supported by extensive physical and chemical tests (§8.4(c), App. 2a-3a, *infra*), as alleged in the complaint and described in a Kolmar affidavit (R. 21-2, 99-102), estimated to cost Kolmar alone between \$8,100,000 and \$42,000,000 (R. 101). FDA estimated 20 years to complete the retesting program for colors (106 Cong. Rec. 14350, June 25, 1960). **

(3) Batches of all cosmetics must be inspected and certified, unless exempt from certification, with a separate fee for each certification (§8.50(j)). Kolmar's estimated cost of a year's certification fees is approximately \$750,000 (R. 101). ***

* While FDA has listed some "diluent" on its own initiative, this does not materially reduce listing fees in view of the hundreds of cosmetic ingredients still unlisted. FDA has recognized that "no final cosmetic product would be prepared from the few diluents" listed by FDA on its own initiative. ("Pretesting of Cosmetics for Consumer Protection" by Miller and Kline, FDA, presented before Tenth Annual Society of Cosmetic Chemists Seminar, Sept. 24-25, 1963.)

** Harvey testified that the testing and detailed information would "be required in connection with applications for listing rouge, leg applications, pancake makeup," and all other finished cosmetic products which color the body (R. 84).

*** The cost of compliance with the Regulations is so incredibly staggering that both courts below assumed the estimates had to be exaggerated (R. 72, 127, fn. 5). Petitioners now argue that compliance costs will not be as high as respondents indicate because the \$2,600 listing fee is a deposit to cover processing costs and "any excesses may be refunded", though such refund is in fact rare.

Petitioners further state there is no requirement that each different shade of lipstick be listed, and that one listing covers all lipsticks produced by a cosmetic manufacturer. (Br. 19, fn. 8). This, however, is contrary to Harvey's testimony that each separate shade of lipstick, or any other cosmetic having varied formulae, would require separate listing (Tr. Dep. 1/21/65, p. 454). Also though the Kolmar affidavit, which states that its 2,700 different finished cosmetic products that color the body must each be listed,

(4) Each manufacturer must maintain complete and separate detailed records (§8.26, App. 3a, *infra*), which for Kolmar would require five additional employees (R. 101-2).

(5) The new requirement for listing finished cosmetic products and their non-color ingredients, with consequent publication of formulae and processes in the Federal Register, would permit appropriation of secret cosmetic formulae by competitors and destroy incentive for costly research and development of new cosmetics (R. 102, 46-7).

The District Court stated in its first opinion that "there can be little doubt but that the added recordkeeping and laboratory testing costs in themselves will be extremely burdensome for all of the plaintiffs", but that aside from the "costs of compliance" "the impact of the regulations on plaintiffs' present methods of doing business will be substantial and give rise almost certainly to potentially greater expenses" (R. 72). It also noted the fact that granting "access to all formulae and processes will have an immediate adverse effect upon further research and development of new products" (R. 72). Its second opinion reaffirmed that "irreparable harm would attach to plaintiffs" (R. 50).

The Court of Appeals noted the allegations of the complaint and the supporting affidavit which described the burdensome impact of the Regulations and the hardship they imposed on the cosmetic industry (R. 127).

was made March 25, 1964 (R. 102), none of petitioners' responsive affidavits ever denied such separate listings are required. On the contrary, Harvey testified that if Kolmar's 2,700 products each had a different formula, as the Kircher affidavit states, each would have to be separately listed, and a separate fee of \$2,600 paid (Tr. Dep. 1/21/65, p. 465). In any event, the burdens and hardship of the Regulations are tremendous, even if Kolmar's estimate of over \$50,000,000 as its cost of compliance should be pessimistic.

Summary of Argument.

1. The question of reviewability must be determined on the allegations of the complaint since the issue is presented by motion to dismiss. The essence of the complaint is that the Regulations exceed the Commissioner's statutory authority and arrogate to him broad powers not granted by statute.

The Regulations are not merely "interpretative" but in effect constitute "legislating" by FDA to obtain the very authority Congress had refused to legislate. However, their label is a matter of form and terminology unrelated to their substance, reach and impact.

There is inherent equity jurisdiction in federal courts to determine the limits of an agency's statutory authority. An actual controversy is presented involving clearcut issues of law and statutory construction appropriate for judicial resolution through injunction and declaratory judgment.

Violation entails severe criminal, civil and multiple seizure penalties. Respondents are not required either to act at their peril and risk such penalties if not sustained, or to comply with regulations deemed illegal and abandon their rights for fear of penalties.

The purpose of the Declaratory Judgments Act was avoidance of such dilemma; it provided an added remedy to the pre-enforcement review available in equity.

Respondents are persons suffering a legal wrong because of final agency action in excess of statutory jurisdiction. Therefore, additional ground for review is authorized by the APA.

Under these circumstances, the complaint presents an actual case and controversy appropriate for judicial resolution in advance of enforcement.

2. The Act contains nothing on its face to establish Congressional intent to withhold prior judicial review or to deny the general review jurisdiction vested in federal courts. The Act provides for a special statutory procedure and direct appeal to a court of appeals, which must affirm agency findings based on substantial evidence. This procedure applies to regulations issued under specified sections of the Act which involve technical matters within the agency's expertise. It is not intended to be exclusive or to establish Congressional intent by implication that other regulations are not reviewable in equity or by declaratory judgment..

Congressional intent to preserve pre-enforcement judicial review was emphasized by the saving clause in the Act which provides that such special statutory procedure is in addition to and not in substitution for any other remedies provided by law. The saving clause is not limited to those regulations to which the special statutory procedure applies. The House Report on the Act emphasizes the right to proceed in equity to enjoin a regulation and to initiate a declaratory judgment proceeding.

3. The Regulations are final, mandatory regulations promulgated pursuant to APA's formal rule-making procedure and impose present obligations on respondents having the force of law. The Regulations apply immediately to finished cosmetic products which impart color to the body, as well as to non-color ingredients and hair dye products exempted from the Act's coverage. There is no basis for petitioners' contention that the provisions of the Regulations requiring the listing and certification of finished cosmetic products do not apply until a future contingent date, after listing and certification of the color ingredient. Accordingly, petitioners' position that the Regulations

impose "no present obligation" and that respondents' injury is "distant and speculative" is groundless.

4. Nor is there basis to petitioners' position that challenge of validity should be by the special statutory procedure. That procedure is limited to factual matters within the agency's special competence. As FDA itself has ruled, its authority to promulgate a regulation presents a question of law which cannot be resolved in an administrative hearing.

The determination of excess of statutory authority does not involve taking evidence, but analysis and interpretation of the Act and its legislative history and comparison with the Regulations. This is traditionally a judicial function appropriate to a court of equity.

5. The Court of Appeals erred in holding the provision as to free access to cosmetic formulae not subject to prior judicial review. The fact that the dilemma of complying with an illegal regulation or risking penalties of non-compliance is not actually faced until an FDA inspector seeks free access against a particular respondent is not sufficient to preclude judicial review. Equity has jurisdiction to anticipate and prevent impending injury by unlawful action. Relief may be granted against excess of statutory authority though not presently directed against a particular party.

The "free access" provision does not stand alone. It is interrelated with the other three challenged provisions as elements of a common plan of governmental regulation, and all four should be reviewed together.

6. *Abbott Laboratories* (No. 39) presents a different situation. Affirmance there would not control the case at bar because of the substantially different nature of the Color Additives Regulations.

The four challenged provisions of the Regulations are clearly reviewable by injunction, declaratory judgment and under the APA. Petitioners should not be permitted to hold an entire industry at hazard by preventing immediate and direct test of the validity of the Regulations. The case should be remanded to the District Court for decision on the merits as to the four challenged provisions.

Argument.

I.

The Regulations are reviewable in this action.

A basic defect in petitioners' position* is its misconception of the complaint, described as merely seeking a declaration that the Regulations are "an unauthorized interpretation" of the Amendments (Br. 5). The complaint, however, alleges that by final mandatory regulation, effective immediately, FDA imposed substantial and highly burdensome obligations on the cosmetic industry "in excess of the statutory jurisdiction, authority and limitations of the defendants" (R. 2, 20, 29, 36, 40), and that "the Commissioner arrogated to himself a power and authority not granted" by Congress (R. 20, 28, 35, ~~39~~ 40) in defiance of specific Congressional action withholding the power. Since the reviewability issue is presented on a motion to dismiss,

* Petitioners appear to incorporate the arguments in the Government's brief in *Abbott Laboratories*, No. 39 (Br. 13), without indicating which portions apply to the Color Additives Regulations. We assume that that brief (the "Abb. Br.") will be adequately replied to by petitioners in that case. Accordingly, respondents will make only occasional reference thereto.

such allegations must be taken as true.* *Joint Anti-Fascist Refugee Committee v. McGrath*, 341 U. S. 123, 126 (1951); *Columbia Broadcasting System, Inc. v. United States*, 316 U. S. 407, 414 (1942); *Stark v. Wickard*, 321 U. S. 288, 305, 311 (1944).

A. The Regulations Are Not "Interpretative" But Are Legislative or Substantive Regulations Which Purport to Have the Force of Law. However, Even If Deemed Interpretative, They Are Subject to Pre-Enforcement Judicial Review.

(1) It is petitioners' basic contention that the Regulations, entitled, "Definitions * * * and Interpretative Regulations," are merely "interpretative"*** and therefore, not subject to pre-enforcement judicial review,—a position the District Court stated "smacks of hypertechnicality" (R. 49). The Court of Appeals saw "little profit in debating the point * * * whether the Regulations are 'interpretative' or 'legislative'," and held "the interpretative character of a regulation does not necessarily make it unripe for review" (R. 134-5).

Petitioners' *Abbott Laboratories* brief describes interpretative regulations as voluntary guides to industry. Examples there given relate to "use in drug manufacture of ox bile from condemned livers of slaughtered animals" (21 C.F.R. 3.16), and "the quantity of egg which must be

* On the renewed motion to dismiss the District Court, in view of the extensive discovery after denial of the first motion, had before it substantial evidence to support the allegations, as well as the legislative history. These led it to observe that the Regulations "rather markedly depart from what preliminarily appears to be the plain legislative authority conferred by Congress" (R.51).

** Interpretative regulations are a defined category, included in Title 21 of the Code of Federal Regulations as "Part 3—Statements of General Policy or Interpretation." APA's rulemaking procedure does "not apply (A) to interpretative rules, general statements of policy" (§4(a), 5 U.S.C. §553(b).)

present in a shampoo preparation for it to qualify as 'egg shampoo' " (21 C.F.R. 3.651) (Abb. Br. 32).

Petitioners equate such interpretative regulations to both the drug regulations in *Abbott Laboratories*, and the Color Additives Regulations,* and argue pre-enforcement challenge would "substantially affect the administration of the Food and Drug Act" (Abb. Br. 32). However, it is obvious that the formal Regulations,—with their broad scope and arrogation of substantial and far-reaching powers to FDA,—are vastly different from an interpretative regulation as to the egg requirements of a shampoo.

(2) Nor can petitioners escape review by calling the Regulations "Definitions."

The "Definitions" section of a statute can determine its reach and intended agency authority. Rarely, if ever, would a statute specifically provide for judicial review of a regulation purporting to "interpret" a "definition." Yet, a change in statutory definition, by "interpretative" regulation, could be the most effective method to expand agency authority.**

Premier Peat Moss Corporation v. United States, 147 F. Supp. 169 (S.D. N.Y. 1956), *aff'd*, 355 U.S. 13 (1957) exemplifies how arbitrary "interpretation" or "definition" can expand agency power. There the court,—illustrating how

* Though petitioners argue the Color Additives Regulations are mere statements of general policy or interpretation, they were not included in Part 3 of the C.F.R., but in Part 8.

** For example, FDA has jurisdiction over "devices," defined as any "apparatus" which affects the body's structure (§201(h)). A bicycle,—which is an "apparatus" and can affect and improve the body's structure,—fits the definition of "device" more aptly than a finished cosmetic product fits the definition of color additive. If FDA, by regulation, "interpreted" the "devices" definition to include bicycles and thereby subjected them to all the Act's provisions applicable to "devices," bicycle manufacturers clearly could obtain prior judicial review of whether FDA had gone beyond Congressional intent and exceeded its statutory authority.

an interpretation "that tomatoes are not an 'agricultural' commodity" would change the coverage of the Interstate Commerce Act as to a tomato farmer and "deprive him of a statutory right,"—sustained prior judicial review of an "interpretation" that the statutory term "agricultural commodities" did not include peat moss, and held that "the Commission exceeded the limits placed upon its statutory powers" (pp. 172, 174).

Similarly, an FDA "definition" or "interpretation" that "color additive" means lipstick, rouge, eye make-up color and other finished cosmetic products which color the body, immediately affects all cosmetic manufacturers and deprives them of a statutory right.

(3) Furthermore, the Regulations are legislative in nature. They were issued under the "authority" of Sections 701 and 706 of the Act (21 C.F.R., 1966 rev., p. 76). Section 706 authorizes the Secretary "by regulation" to provide for listing and certification of color additives.

Section 701(a), in the 1938 Act, has remained unchanged. Section 706 was derived from Sections 406(b), 504 and 604 of the 1938 Act (52 Stat. 1040), which also authorized the Secretary to "promulgate regulations" for listing and certification. The House Report on the 1938 Act* summarizes its provisions as to regulations for listing and states (pp. 9-10):

"Such regulations are not merely interpretive. They have the force and effect of law and must be observed. Their violation may result in the imposition of criminal penalties, or in the confiscation of the goods involved if shipped in interstate commerce, or in their exclusion from the country if imported."

* H. R. No. 2139, 75th Cong., 3d Sess., Apr. 14, 1938, U. S. Cong., House Reports on Public Bills, Serial 10234.

Davis, *Administrative Law Treatise*, states as to "legislative" rules (Vol. 1, §5.03):

"A legislative rule is the product of an exercise of legislative power by an administrative agency, pursuant to a grant of legislative power by the legislative body. * * * A legislative rule is valid and is as binding upon a court as a statute if it is (a) *within the granted power*, * * *." (p. 299)

The "Final Report of the Attorney General's Committee on Administrative Procedure" (1941), using the term "substantive" rather than "legislative" regulation, states that such "regulations have many of the attributes of statutes themselves and are well described as subordinate legislation," (p. 27)

As already noted, FDA proceeded as though it were promulgating regulations intended to have the force of law, carefully following APA's rule making procedure,—a procedure expressly inapplicable "to interpretative rules." (5 U. S. C. §553(b)).

The legislative character of the Regulations is underscored by the fact that FDA itself regarded the matters covered thereby as so legislative in nature that it repeatedly sought legislation granting it the very authority it finally took by the Regulations (see pp. 17-21, *supra*).

Pertinent is *Federal Communications Commission v. American Broadcasting Co.*, 347 U. S. 284, 296 (1954), where the agency, in the guise of interpreting a statute, promulgated regulations in excess of its authority. This Court voided the regulations, stating:

"Likewise, without success, it urged Congress to amend the law to specifically prohibit them ["give-away" programs]. The Commission now seeks to accomplish the same result through agency regulations. In doing so, *the Commission has overstepped*

the boundaries of interpretation and hence has exceeded its rule-making power."

(4) The test of reviewability is not whether a regulation is "legislative" or "interpretative," but its impact on the persons affected,—whether it operates to control their business affairs and other activities, whether it puts them in the position of complying or risking criminal penalties. Whether FDA calls the Regulations interpretative, legislative, substantive, procedural, statements of policy or opinions or concocts a new label, the impact on respondents is the same.

In *Columbia Broadcasting System, Inc. v. United States*, 316 U. S. 407, 411, 419 (1942), where the "regulation" was described by the Government agency on issuance as merely "the expression of the general policy we will follow", this Court rejected an argument, comparable to that here presented, as "addressed to the form rather than the substance of the order".

The Attorney General's Report states that "interpretations may take the form of 'interpretative rules'"; that they are "of considerable importance; customarily they are accepted as determinative by the public at large"; and that "*if there is disagreement with the agency's view, the question may be presented for determination by a court*" (p. 27). This was the law even before the added protection granted by the APA.

Davis, Administrative Law Treatise, quoting from the Attorney General's Report, reaffirms that interpretative regulations are "subject to challenge in any court proceeding in which their application may be in question" (Vol. 1, §5.04, p. 312).

Petitioners, as the District Court stated, give respondents two choices,—"*complying with them [the Regula-*

tions], at a cost that may prove to be prohibitive for some of the plaintiffs, or ignoring them at the risk of incurring the statutory penalties should the regulations later be held valid" (R. 72). If respondents cannot obtain declaratory adjudication, they must comply; the penalties for non-compliance would be ruinous even if they prevail.*

B. Review of the Regulations is Authorized by an Action in Equity for an Injunction.

As stated in *Terrace v. Thompson*, 263 U.S. 197, 216 (1923), parties "are not obliged to take the risk of prosecution, fines and imprisonment and loss of property in order to secure an adjudication of their rights," and therefore "equitable relief may be had."

Stark v. Wickard, 321 U. S. 288 (1944),—where the complaint sought to enjoin an order of the Secretary of Agriculture as "without statutory authority" (p. 303),—held the power of administrative agencies is "circumscribed by the authority granted" (p. 309); "The responsibility of determining the limits of statutory grants of authority in such instances is a judicial function entrusted to the courts by Congress by the statutes establishing courts and marking

* Petitioners make the amazing statement that seizure of cosmetics for non-compliance with listing requirements would not seriously affect a company's reputation "since it would be quite clear to the public what the basis for the seizure is" (Br. 18, fn. 8). Petitioners cannot seriously believe good will would not be affected by headlines of seizure for adulteration, or that news reporters and cosmetic users would understand the seizure was simply a procedural device to test FDA's interpretation of the Act.

In any event, the complaint alleges that mere institution of proceedings "will have a serious, substantial and adverse effect on the business of the company involved * * * and the reputation and integrity of the manufacturer of such cosmetic, and the good will associated with its name, would be forthwith adversely affected, with serious and costly consequences to its business." (R. 24) This allegation must be accepted as true on this motion to dismiss.

their jurisdiction" (p. 310); and, accordingly, "petitioners have shown a right to a judicial examination of their complaint" (p. 311).

Frozen Food Express v. United States, 351 U. S. 40 (1956), where the issue of excess of statutory authority was also presented by suit for injunction, applies *a fortiori*. The ICC issued a "report and order" advising the motor vehicle industry of those commodities within and outside the statutory term "agricultural commodities,"—an "interpretation" which determined exemption from its licensing requirement. It resisted advance test of validity, claiming judicial review had to await an enforcement proceeding. The lower court held the order not reviewable because not made in exercise of ICC's "rule-making power," but as a "definition of such statutory term" (128 F. Supp. at 377, 378).

This Court, however, reversed, held "the issues raised in the complaint are justiciable" (p. 45), and in language so apposite it could have been written for this case, stated (pp. 43-5):

"The situation here is quite different. The determination by the Commission that a commodity is not an exempt agricultural product *has an immediate and practical impact* on carriers who are transporting the commodities, and on shippers as well. The 'order' of the Commission warns every carrier, who does not have authority from the Commission to transport those commodities, that *it does so at the risk of incurring criminal penalties*. §222(a). * * * The 'order' of the Commission which classifies commodities as exempt or nonexempt is, indeed, *the basis for carriers in ordering and arranging their affairs*. Cf. *Rochester Tel. Corp. v. United States*, 307 U. S. 125, 132. Carriers who are without the appropriate certificate or permit, because they believe they carry exempt com-

modities, *run civil and criminal risks.* * * * The 'order' of the Commission is in substance a 'declaratory' one, see 60 Stat. 240, 5 U. S. C. §1004(d), which touches vital interests of carriers and shippers alike and sets the standard for *shaping the manner in which an important segment of the trucking business will be done.* Cf. *Columbia Broadcasting System v. United States*, 316 U. S. 407. * * * We conclude that the issues raised in the complaint are *justiciable* and that the District Court should adjudicate the merits."

Each factor stated in the italicized language applies to this case precisely; the case is indistinguishable.

Mr. Justice Harlan dissented because the regulation "was not put in the form ordinarily used by the Commission in promulgating regulations" and "nowhere commands" compliance (351 U. S. at 45),—considerations here absent. (See pp. 21-23, *supra*.)*

Equally compelling is *Columbia Broadcasting System, Inc. v. United States*, 316 U. S. 407 (1942).

Columbia Broadcasting System ("CBS"), a nation-wide broadcasting network, had contracts with 123 radio stations licensed by the FCC. The regulations—challenged by CBS

* *Abbott Laboratories v. Celebrezze*, 352 F. 2d 286, 288-9 (3d Cir. 1965) (No. 39), distinguished *Frozen Food Express* on the sole ground it "was reviewed under the statutory scheme for review of I. C. C. orders by a specially constituted District Court; 28 U. S. C. §1336." This distinction is fallacious, since Section 1336 does not affect the requirement, applicable to all cases, of a justiciable issue. It does no more for an ICC order than is required for an injunction or declaratory judgment. Had that section removed the requirement of justiciability, obviously this Court would not have considered that issue in *Frozen Food Express*. The Government, in its petition opposing certiorari in *Abbott Laboratories*, stated "we agree that there may be substance to petitioners' contention that the second reason given by the court of appeals [absence of a justiciable issue under the Declaratory Judgments Act] is inconsistent with *Frozen Food Express v. United States*, 351 U. S. 40" (p. 4).

as "beyond the Commission's statutory authority",—authorized denial of license renewal if the station's contract with CBS had certain proscribed conditions.

This Court's decision meets every argument here made by petitioners:

(1) The FCC regulations,—unlike the FDA Regulations,—were not issued as "final" regulations, but as "nothing more than the expression of the general policy we will follow in exercising our licensing power" (p. 411, fn. 1). This Court stated the argument as to non-reviewability was one "addressed to the form rather than the substance of the order" (p. 419),—an answer to petitioners' claim that the FDA Regulations are an announcement of what FDA "believes" and a mere expression of "difference of view" (Br. 8, 17).

(2) The FCC regulations were not even directed to CBS; they related only to individual radio stations seeking license. The impact on CBS was derivative. Yet, CBS had standing to obtain judicial review because application of the regulations would "seriously disorganize its business" (p. 414). The FDA Regulations specifically apply to and have a direct impact on respondents.

(3) FCC urged that the regulations did not operate of their own force to deny or cancel a license. Petitioners urge that the Regulations are not reviewable because they have not yet been applied to respondents and no enforcement proceedings have been instituted. (Br. 16-17). This Court, however, stated (417-418):

"It is enough that failure to comply with them [the regulations] penalizes licensees, and appellant, with whom they contract. *If an administrative order has*

that effect it is reviewable and it does not cease to be so merely because it is not certain whether the Commission will institute proceedings to enforce the penalty incurred under its regulations for noncompliance"

C. Review of the Regulations is Authorized by the Declaratory Judgments Act.

The Declaratory Judgments Act was particularly designed to cover the very situation here presented:

"The [declaratory judgment] procedure has been especially useful in avoiding the necessity, now so often present, of having to act at one's peril or to act on one's own interpretation of his rights, or abandon one's rights because of a fear of incurring damages. So now it is often necessary, in the absence of the declaratory judgment procedure, to violate a statute in order to obtain a judicial determination of its meaning or validity." S. Rep. No. 1005, 73d Cong., 2d Sess., pp. 2-3 (1934).

Declaratory judgment has special application to agency regulations imposing burdens. Thus, as Borchard states:*

"Possibly in no branch of litigation is the declaration more useful than in the relations between the citizen and the administration. . . .; [a] field of controversy peculiarly susceptible to the expeditious and pacifying ministrations of the declaratory judgment."

"In the twentieth century, . . . there has been a special need for a speedy determination of the constitutionality and construction of legislation and regulations imposing burdens on the individual."

*"Challenging 'Penal' Statutes by Declaratory Action," 52 Yale L. J. 445, 454 (1943).

The Declaratory Judgments Act provided an added remedy "to challenge the validity and scope of the agency's order * * * *even if the agency is not prepared to institute court proceedings to achieve compliance*" (*United States v. St. Regis Paper Co.*, 285 F. 2d 607, 615 (2d Cir. 1960), *aff'd*, 368 U. S. 208 (1961)). This Court there indicated that validity of agency orders can be tested by " 'the Declaratory Judgment Act, the Administrative Procedure Act, or general equitable powers of the courts' " "instead of waiting for the Attorney General to sue," "where such orders appear suspect and ruinous penalties would be sustained pending a good faith test of their validity" (pp. 226-7).

See also, *Joint Anti-Fascist Refugee Committee v. McGrath*, 341 U. S. 123, 156 (1951); *Wallace v. Currin*, 95 F. 2d 856, 861 (4th Cir. 1938), *aff'd*, 306 U. S. 1 (1939).

D. Review of the Regulations is authorized by the Administrative Procedure Act.

This action is authorized by Section 10 of the APA (5 U. S. C. §§701-706,—an Act "to be given a 'hospitable' interpretation" (*Shaughnessy v. Pedreiro*, 349 U. S. 48, 51 (1955)). It authorizes judicial review of agency action by "any applicable form of legal action, *including actions for declaratory judgments* * * * in a court of competent jurisdiction." (§703) It "sets forth a simplified statement of judicial review designed to afford a remedy for every legal wrong."*

The APA further authorizes "the reviewing court" to (§706):

"(2) hold unlawful and set aside agency action, findings, and conclusions found to be (A) * * * not

* H. Rpt. No. 1980, May 3, 1946, U. S. Code Cong. Adm. News (1946), p. 1205.

in accordance with law; * * * (C) *in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; * * **

FDA is an agency subject to the APA (§551(1)); the Regulations are within the definition of "rule" (§551(4)); their issuance is "agency action" (§551(13)); and respondents are "adversely affected" (§702). *Flemming v. Florida Citrus Exchange*, 358 U. S. 153, 168 (1958).

Though availability of judicial review is amply established in equity and by the Declaratory Judgments Act, *Heikkila v. Barber*, 345 U. S. 229, 232 (1953), indicates probable expansion of judicial review under the APA. This Court there stated that "the broadly remedial purposes of the Act counsel a judicial attitude of hospitality towards the claim that §10 greatly expanded the availability of judicial review."

Ewing v. Mytinger & Casselberry, 339 U. S. 594 (1950), on which petitioners place such reliance (Abb. Br. 7, 24-5, 30, 45, 47; Br. 14), is not remotely in point. The issue there was not reviewability of a final agency regulation, but of an agency's finding of "probable cause," prerequisite to filing a libel action for misbranding. This Court described such finding as "a preliminary step in a judicial proceeding" and the request for such review as "unique" (339 U. S. at 600). The effect of granting judicial review would have been to "stay the institution of seizures" of products then being marketed, denying the public the "speedy protection which Congress provided by multiple seizures" (p. 601).

Such considerations are obviously not present here. On the contrary, judicial review of the Regulations in this declaratory proceeding will assure not only the public but all concerned the speediest possible resolution of the disputed issues.

II.

Congress did not intend to preclude pre-enforcement judicial review of FDA regulations challenged as in excess of statutory authority. This is shown on the face of the Act and in its legislative history.

It is petitioners' cornerstone contention that the Act contains a " 'highly selective' pattern of review—marked by Congress' specific enumeration of instances when it wished pre-enforcement judicial review and its *silence* when it did not" (Br. 14). They maintain that the only regulations Congress intended be so reviewed are those issued under sections specified in Section 701(e)(1), or those issued under a section which specifically applies Section 701(e)(1), such as Section 706(d), and as to which review is by administrative hearing (the "special statutory procedure"), with direct appeal to the Court of Appeals which must treat the agency's findings as conclusive "if supported by substantial evidence".

Asserting the Act is silent as to pre-enforcement judicial review of all other regulations, petitioners find what is "characterized as 'implied statutory exclusion' of judicial review." (Abb. Br. 23).

Petitioners overlook certain fundamental considerations.

First, the responsibility of determining whether an agency exceeded statutory authority is a judicial function. Mere silence as to judicial review is not construed as denial of authority to aggrieved persons to seek relief in the federal courts in exercise of their general jurisdiction. *Stark v. Wickard*, 321 U. S. 288, 309-10 (1944). To preclude such judicial review of a regulation, the statute " 'must upon its face give clear and convincing evidence of an intent

to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of an intent to withhold review.' " *Heikkila v. Barber*, 345 U. S. 229, 232 (1953).

The Act does not on its face contain any evidence of Congressional intent to withhold judicial review or to deny the general review jurisdiction vested in the federal courts. Neither the alleged " 'implied statutory exclusion' of judicial review " nor "the legislative history" upon which petitioners rely (Abb. Br. 11-26) satisfies the test that Congressional intent must appear on the face of the statute by clear and convincing evidence.

In *Gonzalez v. Freeman*, 334 F. 2d 570 (D. C. Cir. 1964), to defeat challenge to agency regulations as in excess of statutory authority, it was also urged that since the applicable statute,—the Commodity Credit Corporation Act (15 U. S. C. §714(b)),—was silent as to judicial review, this showed none was intended. The Court held (334 F. 2d at 575):

"We find no such intent reflected in the statute.
* * * 'the responsibility of determining the limits of statutory grants of authority in such instances is a judicial function entrusted to the courts by Congress
* * *' *Stark v. Wickard*, 321 U. S. 288, 310, 64 S. Ct. 559, 571, 88 L. Ed. 733 (1944).

"* * * Nothing in the statute confers unreviewable finality on determinations of the Secretary as to questions of the scope of his congressional authority * * *."

Second, as the Court of Appeals stated, "The agency determinations specifically reviewable under §701(e)* re-

* Section 701(e) (1) covers §401, as to standards of identity and quality for food; §403(j), as to labeling information for a food's

late to . . . technical subjects" within FDA's expertise, and Congress "did not wish courts to consider such matters without the benefit of the agency's views after an evidentiary hearing before it" (R. 129-30). However, the scope of the Commissioner's statutory authority is a legal issue as to which the court rather than the agency has the requisite expertise.

Third, the Act is not silent as to other remedies. It plainly provides in the Section 701(f) saving clause that:

"(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law".

The House Report on the 1938 Act* stressed that "any individual or business organization" affected by FDA regulations may proceed by declaratory judgment and suit for injunction to enable prompt determination of their validity and certainty as to legal rights. Thus, the Report, referring to the saving clause, states (p. 11):

"There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding."

Petitioners nevertheless argue that the saving clause applies only to regulations specifically made reviewable

vitamin, mineral and other dietary properties; §404(a), as to food contamination during manufacturing or packing; §406, as to limiting poisonous substances required in food production; §501(b), as to testing strength, quality and purity of certain drugs; §502(d), as to drugs, containing habit forming narcotics; §502(h), as to packaging drugs liable to deterioration; and §706 as to listing and certifying colors, including quantity of a dye which may be safely used in food, drugs and cosmetics, the cumulative effect of such dye in the diet of man or animals, and like technical matters.

* Rep. No. 2139, 75th Cong., 3d Sess., dated April 14, 1938.

under Section 701(e) (Abb. Br. 26-7),—a narrow construction not accepted by either court below; both held such clause preserved all other remedies provided by law (R. 52, 139).^{*} The saving clause was obviously designed to preserve the broadest possible judicial review, as its legislative history so clearly establishes. It foreclosed a construction that the special statutory procedure precluded appropriate relief in the federal courts (*Cf. Stark v. Wickard*, 321 U. S. 288, 309 (1944)), and made it clear that even as to those regulations to which the special statutory procedure applied, the aggrieved person could proceed in equity by declaratory judgment or any other remedy provided by law.

Petitioners' position would produce an anomalous result. It would provide two types of review for regulations covered by Section 701(e)(1) and deny all pre-enforcement review of a regulation whereby the agency exceeded its powers.

There was no need for Congress expressly to preserve judicial review of challenge of statutory authority, since the power of review in equity by injunction and declaratory judgment is inherent in federal courts and implicit as to every agency, unless a statute on its face specifically withholds such judicial review or expressly prescribes a special and exclusive remedy.^{**} *Stark v. Wickard*,

^{*} The Court of Appeals noted (R. 130, fn. 7) that the accompanying minority report "indicated that the special procedure was understood to be an additional protection for industry and not an exclusive method of review of all actions for the benefit of the agency. H.R. Rep. 2139, Pt. 2 (April 21, 1938)."

^{**} The Government itself brings this out in its *Abbott Laboratories* brief (p. 13), which notes that the House considered it unnecessary to incorporate a review provision because "[t]here is always an appropriate remedy in equity . . . and furthermore the committee is of the opinion that ample protection is given by the so-called Declaratory Judgments Act . . ." H. Rep. No. 2755, 74th Cong., 2d Sess. (1936), p. 8, *Dunn* 557."

321 U. S. 288, 309-10 (1944); *Heikkila v. Barber*, 345 U. S. 229, 232 (1953). The House Report emphasized that the fact the Act did not affirmatively deny judicial review to FDA regulations indicated an intent to authorize the broadest kind of judicial review and to hold a regulation invalid "if for any other reason it was not in accordance with the law" (Rept. No. 2139, p. 12):

*"The committee amendment is silent as to any limitations on the court in holding invalid the order of the Secretary. The court is thus left free to exercise its right of review to the full extent that it may constitutionally do so. * * *"*

It is clear beyond question, as the Court of Appeals stated, that Section 701 does not indicate Congressional intent "to insulate administrative action not covered by subsection (e) from challenge as in excess of statutory authority" (R. 130).

III.

The Regulations have immediate impact on respondents and are ripe for judicial review.

Petitioners argue that only after the color ingredient in the cosmetic has been listed and certified will the question arise "whether respondents must also obtain separate listing and certification or exemption therefrom for their particular finished color-imparting cosmetics before these products may be offered for sale" (Br. 17). Then "the issue of statutory construction will be squarely presented, in a concrete case, to a court of appeals" under the special statutory procedure (Br. 18). Therefore, "no present obli-

gation" is imposed on respondents and their "injury is distant and speculative" (Br. 17).

This argument misdescribes the Regulations and bears no relationship to their text or announced purposes or to FDA testimony as to their meaning and impact.

The Act is plain. It pronounces as adulterated and prohibits sale of any article of food, drug or cosmetic containing a color additive not listed in a regulation and certified, unless exempted (§304(a), 601(e), 706(a)). This applies immediately to everything that is a color additive. The Regulations, defining color additive to include not only the color but the finished cosmetic product which contains the color, became "effective on the date of its publication in the Federal Register", June 22, 1963, though the portions as to diluents and hair dyes were made effective, respectively, one and two years later (28 Fed. Reg. 6439, 6449). When FDA defined "color additive" to include "Lipstick, rouge, eye make-up colors, and related cosmetics intended for coloring the human body" (§8.1(f)), the listing and certification requirements automatically became applicable to such cosmetics at the same time they became applicable to the dye, pigment or other color ingredient.

There is nothing in the Regulations which provides, or even suggests, that the listing requirement applies at one time to the color ingredient and at a later time to the cosmetic product itself.*

*Respondents, in compliance with the requirement for listing dyes and pigments, had by December 3, 1965, filed petitions to list 16 separate colors "for use in drugs and cosmetics that are applied externally" (R. 94-5). A Government affidavit states that "Because of the pendency of this lawsuit, these petitions have not yet been acted upon" (R. 97). This is inconsistent with petitioners' position that the Regulations first require listing of the color, and thereafter, at some future date, possible separate listing of the cosmetic containing the color. If listing of colors, which it is agreed is required by the Amendments and the Regulations, must

The "present obligation" and burdens of the Regulations have been described (pp. 23-25, *supra*). The required testing of finished cosmetic products, prerequisite to listing, would have to be promptly commenced and diligently pursued. The Regulations have "an immediate and practical impact" on the entire cosmetic industry and set "the standard for shaping the manner in which" its business is operated. *Frozen Food Express v. United States*, 351 U.S. 40, 44 (1956).

The Court of Appeals correctly held the Regulations have "immediate impact on the industry, posing the unacceptable alternatives of complying or of incurring possible forfeitures and criminal liability, and calling into question long standing practices of premarketing testing and clearance" (R. 136). Respondents' injury is not "distant."

However, even if petitioners correctly describe the Regulations as delaying listing of the finished product until after listing of the color ingredient, that would not make the Regulations unripe for review. In *Flemming v. Florida Citrus Exchange*, 358 U. S. 153, 168 (1958), where legislation delayed for three years the effectiveness of the Secretary's order delisting certain colors, this Court held "the facts of the respondents' business are such that if the order is upheld, there will be a practical effect on them even during the span of the temporary legislation" and, accordingly, "it is proper for us now to determine the legal situation in regard to them when the temporary legislation expires."

Nor is there basis to the argument respondents' injury

precede listing the finished cosmetic product, there is no reason why action on the color listing petitions should be delayed merely because respondents challenge FDA's power to require listing of the finished cosmetics.

is "speculative" because FDA might never require separate listing and certification of the finished cosmetics. If such products are in fact color additives, as the Regulations provide, then listing is mandatory, even for cosmetics in use for over 50 years and generally recognized by qualified experts as safe. The Act grants FDA power to exempt color additives only from certification, not from listing.

The Regulations are neither "distant" nor "speculative" and are ripe for judicial review.

IV.

The special statutory procedure is inapplicable to the issue of excess of authority.

Petitioners suggest that if in the future the provision requiring listing of finished cosmetic products is applied to a particular respondent, he can follow "the administrative procedure specifically authorized under the statute", and then "the issue of statutory construction will be squarely presented, in a concrete case, to a court of appeals under the judicial review procedures of Section 706(d), which incorporates Sections 701(e), (f) and (g)" (Br. 16, 18). However, the special statutory procedure is clearly not designed to adjudicate issues of exceeding statutory authority. As the District Court stated, "it is scarcely to be thought that judicial review limited to the traditional and narrow scope of whether or not the Commissioner's findings are supported by adequate evidence can supplant the other and broader form of remedy or review available under the Declaratory Judgment Act." (R. 52)

Existence of special agency procedures does not require an aggrieved party to first go before the agency where, as

here, the issue is exceeding statutory power. In *Skinner & Eddy Corp. v. United States*, 249 U. S. 557 (1919), this Court held that a party challenging ICC orders could proceed immediately in the district court because "The contention is that the Commission has exceeded its statutory powers; and that, hence, the order is void. In such a case the courts have jurisdiction of suits to enjoin the enforcement of an order, even if the plaintiff has not attempted to secure redress in a proceeding before the Commission" (p. 562).

Nowhere do petitioners indicate how an issue of excess of statutory authority is even presented in FDA's special statutory procedure. Assuming FDA should by regulation list a particular dye for use in a lipstick and specify the tolerance or quantity used, and a cosmetic manufacturer filed objections urging a different quantity, how could this conceivably present the issue whether FDA has power to require that the finished cosmetic product itself be listed and subjected to the certification requirement?

FDA itself has taken the position such an issue could not be determined in an agency hearing. When challenge was made to the Commissioner's authority to promulgate certain regulations under the "Drug Abuse Control Amendments of 1965" (79 Stat. 226), which authorized regulations as to depressant and stimulant drugs with review under the special statutory procedure, the Commissioner refused even to allow the objections to be filed since they were "concerned with the Commissioner's authority under the act to promulgate the inventory requirement regulations. *This is a question of law and cannot be resolved by the taking of evidence at a public hearing.*" (31 Fed. Reg. 7174, May 17, 1966).

In fact, petitioners, disagreeing with the District Court's decision to have a trial (R. 75-76), now assert "that the issues of statutory construction can be resolved without evidentiary proceedings and that the record is now adequate to resolve them."* (Br. 20, fn. 9). This statement is irreconcilable with their position that respondents are limited, absent an actual enforcement proceeding, to an administrative hearing with direct review in the court of appeals.

V.

FDA arrogation of power to obtain "free access" to cosmetic formulae is also subject to judicial review in equity, by declaratory judgment and under the APA.

The Court of Appeals, without the issue having been separately considered, held the "free access" provision not reviewable. The correctness of this is the subject of No. 336.

The "free access" provision differs from the others in one primary respect. Compliance with the listing obligation requires immediate action by all respondents, who would have to commence testing and file petitions. The "free access" clause, however, requires nothing of respondents until arrival of the FDA inspector, when the decision

*Petitioners took the opposite position in the District Court. They there successfully opposed summary judgment with the curious argument that "The substantive issue . . . is whether defendants have exceeded their statutory authority in promulgating the specific regulations here at issue. This issue requires an examination of the statute and the applicable regulations, the recognition of clearly delineated legal principles and the application of common sense and reason. Accordingly, defendants do not regard summary judgment as an appropriate procedural remedy . . .". (Defendants' Memo. in opposition to Plaintiffs' Motion for Summary Judgment, undated, pp. 49-50).

must be made either to allow access and abandon rights for fear of penalties or deny access and face penalties.

The Court of Appeals held the issue remote and, therefore, found unripeness; each reason given (R. 137-8) is in conflict with applicable decisions of this Court.

A. The Permissive Language of the "Free Access" Provision and the Fact It Does Not Impose a Present Obligation on Respondents Do Not Preclude Judicial Review.

The "free access" provision was also promulgated pursuant to APA's rulemaking procedure; general notice of proposed rulemaking was published, ostensibly to enable interested persons to comment;* and the final provision was published June 22, 1963, effective immediately. (See pp. 21-23, *supra*.)

As shown above (pp. 17-21), FDA long wanted access to food and cosmetics formulae and in 1962 sponsored legislation to "remedy this problem" of denial of access, and allow "complete inspection" of all processes. After Congress limited inspection of processes and formulae to prescription drugs, and a new FDA attempt the following year also failed, FDA took the "free access" power, warning that refusal of access could cause the cosmetic to be banned from the market (R. 106-7).

FDA counsel Goodrich had stated "the need is real" and FDA will "continue with all our abilities to urge the Congress to meet the need."** (See p. 20, *supra*.)

* As already noted, the provision giving "free access" to formulae of finished cosmetic products was not in the original notice of proposed rule-making (p. 22, *fn. supra*).

** Petitioners' original brief in the District Court, undated, and served March 3, 1964, pp. 49, 50, also stressed FDA's need for "free access" to cosmetic formulae, making substantially the same argument FDA had presented to Congress; namely, that such access was "plainly needful for the effective enforcement of the

Such assertions, coupled with its persistence in seeking the "free access" authority from Congress, makes it unlikely FDA will refrain from exercising the power taken by regulation. It is unrealistic to assume, as the court below did, that the possibility is "remote" because "No one can now say whether the Commissioner will ever make a demand for free access" (R. 137).

FDA use of "may" rather than "will" can hardly soften the impact on the cosmetic industry of the power it illegally took or its warning it may "ban it [the product] from the market" (R. 106-7).

Vicksburg Waterworks Co. v. Vicksburg, 185 U. S. 65, 82 (1902) rejected a contention that "mere apprehension that illegal action may be taken" was insufficient basis to enjoin such action, and held "it is one of the most valuable features of equity jurisdiction, to anticipate and prevent a threatened injury," and to protect a party "from injuries which, if inflicted, would be wholly destructive of his rights."

Similarly, *Pierce v. Society of Sisters*, 268 U. S. 510, 536 (1925) held that suit to enjoin a statute not to become effective for four years was not premature, and that "Prevention of impending injury by unlawful action is a well recognized function of courts of equity."

In *Joint Anti-Fascist Refugee Committee v. McGrath*, 341 U.S. 123, 141 (1951) where, as at bar, the official charged

Act," and that the Commissioner "must have access to the plants where they [the cosmetics] are made" and to cosmetic formulae, since "There is no other way in which the Commissioner" can perform his functions.

Similarly, affidavits of Oscar Garth Fitzhugh and Kenneth A. Freeman, of FDA's Bureau of Scientific Standards and Evaluations, sworn to, respectively, May 26, 1964 and May 22, 1964, submitted in support of the "free access" regulation, stated that FDA "must know the exact formula of the product" (Fitzhugh, ¶2), and that "it is necessary that we have a full disclosure of all the ingredients in any color additive," defined to mean finished cosmetic products (Freeman, ¶4).

with exceeding statutory authority did nothing directly affecting the petitioners, this Court stated "We long have granted relief to parties whose legal rights have been violated by unlawful public action, *although such action made no direct demands upon them.*"

Particularly pertinent is *Columbia Broadcasting System, Inc. v. United States*, 316 U.S. 407 (1942). There the regulations were not issued as "final", nowhere demanded compliance and, as in the case of the "free access" provision, required action by the agency. This Court, however, held the regulations were subject to prior judicial review even though they "are not directed to appellant and do not in terms compel action by it or impose penalties upon it because of its action or failure to act" (p. 422). It further held that reviewability was unaffected by the fact that the regulations were "not directed to any particular person or corporation," or that "their promulgation did not operate of their own force * * *" (p. 417). "*Such regulations have the force of law before their sanctions are invoked as well as after*" (p. 418).

The holding below that the "free access" regulation is not ripe for review because it merely warns that "the Commissioner may—not that he inevitably will" enforce the regulation, is as stated in that case, "addressed to the form rather than the substance" (p. 419).

This Court also held that an administrative order is reviewable where there is risk of penalty, and "it does not cease to be so merely because it is not certain whether the Commission will institute proceedings to enforce the penalty * * *" (pp. 417-8). This Court also said,—in language which answers the Court of Appeals' statement that "No one can now say * * * whether any manufacturer will ever decline" requested access (R. 137), that:

"It is common experience that men conform their conduct to regulations by governmental authority so as to avoid the unpleasant legal consequences which failure to conform entails" (p. 418);

"* * * the expected conformity to them causes injury cognizable by a court of equity" (p. 419).

Reviewability of the "free access" clause is also unaffected by the fact that the Regulation is not couched as a direct grant of access authority but indirectly accomplishes the same result, through the penalty of banning the product from the market, with all the consequences attendant on illegal sale.^{*} For, as this Court stated, "it is the substance of what the [agency] has purported to do and has done, which is decisive" (p. 416).

Equally apt is *Frozen Food Express v. United States*, 351 U. S. 40 (1956) where the regulation, as Mr. Justice Harlan's dissent noted, likewise "nowhere commands" compliance (p. 45). This Court, sustained reviewability because the order, which was issued as an announcement rather than a final regulation, "warns" the industry that violation would involve "the risk of incurring criminal penalties," so that it is not "abstract, theoretical, or academic," but "touches vital interests" of the industry there involved (p. 44),—language which shows the error in the decision below that this "free access" regulation is not reviewable because it "simply warns the industry" (R. 137).

* Had FDA used in the Regulations the exact language of the 1962 proposed amendment which Congress had deleted, there still would be "nothing to indicate that the Commissioner intends to invoke the factory inspection provision in any particular case" (Br. 21). The proposed amendment merely "authorized" inspection (§704(a)). It was no less permissive in language, or more certain as to the person against whom it might be directed than the "free access" provision. Yet, in such event the usurpation of power would be so crude, it is unlikely any court would use the permissive aspect to deny pre-enforcement judicial review.

In *United States v. Storer Broadcasting Co.*, 351 U. S. 192 (1956), "ripeness" for review was found although, as the dissent noted, the petitioner did not allege "present injury of any kind", the challenged regulations "impose no duty" and there was no "possibility of criminal penalties" (pp. 209, 212, 212 fn. 3). There this Court also noted that in the *Columbia Broadcasting System* case the regulation held reviewable "did not command CBS to do or refrain from doing anything" (p. 198).

B. Availability of an FDA Hearing Does Not Preclude Pre-Enforcement Judicial Review.

The court below denied reviewability partly because of availability of an FDA hearing, with possible review by a court of appeals (R. 137), an argument petitioners also now urge (Br. 21). However, the hearing authorized by the Regulations relates only to "the factual basis for the suspension" §8.28(b). If court of appeals review should be available, the findings as to the "factual basis" for banning the cosmetic from the market, "if supported by substantial evidence, shall be conclusive" (§701(f)(3)).

The factual basis for suspension would be self-evident; namely, the manufacturer's refusal to permit "free access" to cosmetic formulae and trade secrets. The only issue in an FDA hearing would be whether access was denied, as to which there would be no dispute. The hearing would not even present the issue whether FDA had exceeded its statutory authority. As noted above, FDA takes the position that the issue of its authority under the Act "is a question of law and cannot be resolved by the taking of evidence at a public hearing." (p. 50, *supra*). The only issue in the court of appeals would be whether there was substantial evidence that FDA access had been denied.

The above discussion as to the first three challenged provisions establishing that the special statutory procedure to review FDA regulations is inappropriate to review issues of exceeding authority and, in any event, is not the exclusive remedy (pp. 49-51, *supra*), applies equally to the issue of FDA's power to require "free access" to cosmetic formulae.

C. A Proper Declaratory Judgment Can Be Issued.

The court below also stated as a reason for not reviewing the "free access" regulation, that "it is impossible to see what declaration a court could properly make" (R. 137), —a point not raised below in briefs or oral argument. The answer is simple. The declaration would be that the provisions of §§8.1(f) and 8.28(a)(4) of the Regulations granting "free access" to cosmetic formulae and processes are not authorized by the Act and are in excess of statutory authority. In effect, these provisions would be deemed deleted from the Regulations.

It should be no ground for refusing to hear a declaratory judgment action that an appellate court may have difficulty at the threshold, and without the merits before it, to see what declaration the District Court could make on the merits, especially when the District Court saw no such difficulty and found "compelling reasons for assuming jurisdiction" (R. 73).

D. The Desirability of Reviewing the Four Provisions of the Regulations Together.

One final significant factor may be noted. Were the only illegal provision the "free access" provision it would be reviewable. However, the reasons for review are heightened, and apply *a fortiori*, because this provision does not stand alone but, as the District Court so aptly stated, "these

four provisions are interrelated as elements of a common plan of governmental regulation" and "there is a distinct advantage in reviewing them together" (R. 73).

The Court of Appeals erred in reversing as to the "free access" provision, which, as may be parenthetically noted, satisfies every test contained in the APA (pp. 40-41, *supra*). Such provision should be reviewed, together with the three other challenged provisions of the Regulations.

VI.

The Abbott Laboratories case presents an entirely different type of regulation from the Color Additives Regulations and is distinguishable.

While the *Abbott Laboratories* case and the case at bar both broadly involve the issue of pre-enforcement judicial review of agency regulations by injunction, declaratory judgment and under the APA, the cases involve different types of regulations. While respondents believe *Abbott Laboratories* was wrongly decided below, should this Court affirm, that would not control reviewability of the Color Additives Regulations.

Although the Court of Appeals stated *Abbott Laboratories* "is not distinguishable on any satisfying basis" (R. 135), respondents submit that the District Court properly held that the situation at bar "is significantly different" from *Abbott Laboratories* (R. 50).

Abbott Laboratories does not present a regulation whereby FDA took new and different powers from those authorized by the Act. There Congress had imposed a specific requirement on the drug industry, namely, that a drug's generic name be "printed prominently" on its label "in type at least half as large" as any brand or proprietary

name (§502(e)(1)(B)). Congress, therefore, clearly intended the requirement that the generic name appear "prominently". Presumably, this requirement could, as the District Court stated, "be satisfied in a number of ways" (R. 50).

However, under the challenged regulation, FDA provided that the "prominently" requirement could be satisfied only if the generic name appears "each time" the brand or proprietary name is used (21 C.F.R. §1.104(g)(1)). FDA, interpreting the word "prominently", in effect determined there was only one way whereby it could be satisfied, except to the extent exemptions might be established because compliance with such requirement was impracticable (§502(e)(1)(B)). FDA was thus acting in a narrow area of drug labelling, in which Congress had specifically legislated and as to which it intended FDA to function. But FDA took what appears to be arbitrary action contrary to Congressional intent.

The Color Additives Regulations obviously present a "significantly different" situation. Congress never authorized premarketing clearance of cosmetics, or their non-color ingredients, or broad coverage of hair dyes, or access to cosmetic formulae, and never intended FDA to take action in such areas. But by the Regulations, FDA reached out, brought under its control and imposed premarketing clearance requirements on an entire industry, and assumed other authority Congress had repeatedly declined to legislate.

Regardless of this Court's disposition of *Abbott Laboratories*, all four challenged provisions of the Regulations should be held reviewable by injunction, declaratory judgment and under the APA.

Conclusion.

For the foregoing reasons, it is respectfully submitted that the judgment of the Court of Appeals with respect to the First, Second and Third Counts of the complaint should be affirmed, and its judgment with respect to the Fourth Count should be reversed. The case should be remanded to the District Court with instructions to determine whether the four challenged provisions of the Regulations are in excess of statutory authority.

December 30, 1966.

Respectfully submitted,

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APPENDIX.

The Administrative Procedure Act, 60 Stat. 243 (1946), 5 U. S. C. §1001, *et seq.*, recodified in 5 U. S. C. §551, *et seq.* (Public Law 89-554, 80 Stat. 378), provides in pertinent part:

§551. Definitions

For the purpose of this subchapter—

(1) “agency” means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, . . .

(4) “rule” means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. . . .

(13) “agency action” includes the whole or a part of an agency rule. . . .

§553. Rule making

“(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; * * *

§706. Scope of review.

To the extent necessary to decision and when presented, the reviewing court shall * * * (2) hold unlawful and set aside agency action, findings, and conclusions found to be (A) * * * not in accordance with law; * * * (C) in excess of statutory jurisdiction, authority or limitations, or short of statutory right. * * *

Color Additives Regulations.

21 C. F. R. 8.1(f) provides in pertinent part:

A "color additive" is any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting a color thereto. This includes all diluents. * * * A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." * * * For the purposes of this part, the term "color" includes black, white, and intermediate grays, * * *.

21 C. F. R. 8.4 provides in pertinent part:

Petitions proposing regulations for color additives.

(a) Any interested person may propose the listing of a color additive for use in or on any food, drug, or

cosmetic or for coloring the human body. Such proposal shall be made in a petition in the form prescribed in paragraph (c) of this section. . . .

(c) Petitions shall include the following data and be submitted in the following form:

.
D. Full reports of investigations made with respect to the safety of the color additive.

(A petition will be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the color additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any data that would influence the evaluation of the safety of the color additive).

21 C. F. R. 8.26 provides:

Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the color additive from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health, Education, and Welfare, such person, at all reasonable hours until at least 2 years after disposal of all such color additive, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color additive on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by such person from such batch and the date and kind of such use.

(2) The date and quantity of each shipment or delivery from such batch, and the name and post-office address of the person to whom such shipment or delivery was made.

(c) The records required to be kept by paragraph (a) of this section shall be kept separately from all other records.

21 C. F. R. 8.28(a) provides in pertinent part:

Authority to refuse certification service.

(a) When it appears to the Commissioner that a person has:

• • • • •

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived; he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

21 C. F. R. 8.30(a) provides:

Color additive mixtures; certification and exemption from certification.

(a) *Color additive mixtures to be certified.* Any color additive mixture that contains one or more straight colors listed in Subpart C, E, or G, together with any diluents listed in such subparts for use with such straight colors, shall be certified if intended for use in foods, drugs, or cosmetics, or in coloring the human body, as the case may be, subject to any restrictions prescribed in Subparts A and B.

21 C. F. R. 8.50 provides in pertinent part:

Fees for listing.

(a) Each petition for the listing of a color additive shall be accompanied by a deposit of \$3,000.00 if the proposal is for listing the color additive for use generally in or on foods, in or on drugs, and in or on cosmetics.

(b) If the petition for the listing is for use in or on foods only, the deposit shall be \$3,000.00.

(c) If the petition for the listing is for use in or on drugs and/or cosmetics only, the deposit shall be \$2,600.00.

.

(j) The fee for services in listing a diluent under §8.30 for use in color additive mixtures shall be \$250.00.

21 C. F. R. 8.51(a) provides:

Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with §8.22(j) (1) and (2), shall be 15 cents per pound of the batch covered by such requests, but no such fee shall be less than \$100.00.

In the Supreme Court of the United States

OCTOBER TERM, 1966

Nos. 336, 438

**THE TOILET GOODS ASSOCIATION, INC., ET AL.,
PETITIONERS**

v.

**JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, AND JAMES L. GODDARD, COMMIS-
SIONER OF FOOD AND DRUGS**

**JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, AND JAMES L. GODDARD, COMMIS-
SIONER OF FOOD AND DRUGS, PETITIONERS**

v.

THE TOILET GOODS ASSOCIATION, INC., ET AL.

**ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF
APPEALS FOR THE SECOND CIRCUIT**

**REPLY BRIEF FOR RESPONDENTS IN NO. 336 AND FOR
PETITIONERS IN NO. 438**

1. We observed in our main brief (pp. 9-12) that the sole issue on the first three counts of the complaint in this case is whether the statute authorizes

the Food and Drug Administration to require pre-marketing clearance in the form of listing and certification of finished cosmetic products, diluents and certain kinds of hair dyes. We attempted there to distinguish that question from a challenge to the power of the Food and Drug Administration to examine such products as part of an inquiry to determine whether color ingredients contained therein are "safe-for-use."

Although respondents' brief does not squarely take issue with these observations,¹ it occasionally suggests that in enacting the Color Additive Amendments of 1960 Congress did not intend to authorize "pretesting" of finished cosmetic products.² This suggestion is so plainly contrary to the purpose of the 1960 amendments that it cannot go unchallenged.

The 1960 amendments were suggested by the Food and Drug Administration which had been authorized, by this Court's construction of the previous statutory language in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, to bar the use in foods, drugs and cosmetics of any color additive which was not absolutely harmless. In enacting the 1960 amendments, Congress conferred on those responsible for administration of the Act the duty of assuring "the safety of the use or uses

¹ In discussing the "burdens imposed on the cosmetic industry by the regulations" (Resp. Br. 23-25), it enumerates only such "burdens" as are attributable to separate listing and certification. And respondents' discussion of the allegedly "immediate impact" of the regulations also focuses on the effects of a requirement that petitions for listing finished cosmetic products be filed forthwith (Resp. Br. 46-49).

² See Resp. Br. 11, 13, 24, 48.

for which a particular color additive is listed" by prescribing "the conditions under which such additive may be safely employed for such use or uses", including not only specifications regarding maximum quantities but also specifications "as to the manner in which such additive may be added to used in or on" any food, drug or cosmetic. Section 706(b)(3), 21 U.S.C. 376(b)(3).

Nothing could be clearer than that Congress did not intend the Commissioner of Food and Drugs to be limited in his examination to the dye or pigment itself, separate and apart from the food, drug or cosmetic in which it is used. The plain purpose of the law would be defeated by an application of the 1960 Act which so limited the concern of the Food and Drug Administration. Its consequence would be a focussing of attention on the color component itself—separate and apart from its ultimate use in a cosmetic—and this would disable the Commissioner from determining and prescribing the restrictions necessary to insure the "safety in use" of the pigment or dye. Color components are rarely used separately, and the goal of consumer safety could plainly not be realized if only the component were subjected to testing and close scrutiny.

2. We submit, therefore, that "pretesting" of finished cosmetic products and diluents is an essential phase of the administration of the "safety-in-use" standard prescribed by the 1960 Act, irrespective of whether the finished cosmetics are themselves "color additives" so as to require their listing and certification. In determining whether to approve a pigment

or dye as safe for use in a finished cosmetic product, the Food and Drug Administration will ordinarily find it necessary to require the "pretesting" of the finished product and of the diluents it contains. Once the color ingredient is determined to be safe for use under these circumstances, that finding applies necessarily to the finished product as well as to its components. Whether the final product is or is not separately "listed" is, therefore, of no practical consequence, and the Commissioner does not read the statute as requiring separate "listing" of cosmetic formulae in these circumstances.

3. This demonstrates, we submit, how unreal this controversy is at the present time. If respondents submit petitions with adequate supporting material for listing of color ingredients for their specific intended use, and if the Commissioner determines that the particular uses are safe, the ingredients and the finished products will, in effect, be "listed" simultaneously. Nothing in the statute or regulations requires a separate formal paragraph in the Code of Federal Regulations for each "color additive," and listings may be sought and granted together for related products subject to the Act.* Consequently, respondents cannot know today whether the Food and Drug Administration subjected them to any disadvantage whatever as a result of the challenged regulations.

* Cellophane, for example, is a "food additive" when used in food packaging. The substances which may be used in cellophane are enumerated together (21 C.F.R. 121-2507), and there is no separate listing of each of the separate compositions.

4. Respondents' claim that an immediate staggering financial burden is imposed by the certification and listing requirement is totally unreal. Respondents are not obliged to submit 2700 formulae for separate "listing" (Resp. Br. 23-24). Formulae may be grouped according to their common base or common coloring ingredient, and a petition for listing may be submitted for the entire group—subject only to a \$250 fee for each added diluent. See 21 C.F.R. 8.50(j). The \$2600 payment required by 21 C.F.R. 8.50(c) is a deposit which is applied against the Food and Drug Administration's actual costs of processing the petition. If differing formulae requiring substantial additional verification are combined in a single petition the cost may exceed that figure and an added deposit will be requested. If the costs of processing are less than \$2600, the excess will be refunded. The extent of exaggeration in respondents' alleged costs becomes obvious if it is considered in light of the total budget of the Food and Drug Administration. In fiscal 1967, the complete budget was about \$65 million, with only \$1½ million being used for food and color additive preclearance. And it is entirely clear that the costs of chemical pretesting will not even remotely approach the figures cited by respondents (Resp. Br. 24) because that figure is arrived at by the mistaken procedure of multiplying the cost of testing a single cosmetic by the number of cosmetics produced (R. 101). Obviously the substantial similarity among lipstick ingredients, for example, rend-

ers it unnecessary to subject each of the different products to the same test of all components.

Respectfully submitted.

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JANUARY 1967.

SUPREME COURT OF THE UNITED STATES

No. 336.—OCTOBER TERM, 1966.

The Toilet Goods Association,
Inc., et al., Petitioners,

v.

John W. Gardner, Secretary
of Health, Education, and
Welfare, et al.

On Writ of Certiorari to
the United States Court
of Appeals for the Sec-
ond Circuit.

[May 22, 1967.]

MR. JUSTICE HARLAN delivered the opinion of the Court.

Petitioners in this case are the Toilet Goods Association, an organization of cosmetic manufacturers accounting for some 90% of annual American sales in this field, and 39 individual cosmetics manufacturers and distributors. They brought this action in the United States District Court for the Southern District of New York seeking declaratory and injunctive relief against the Secretary of Health, Education, and Welfare and the Commissioner of Food and Drugs, on the ground that certain regulations promulgated by the Commissioner exceeded his statutory authority under the Color Additive Amendments to the Federal Food, Drug, and Cosmetic Act, 74 Stat. 397, 21 U. S. C. §§ 321-376. The District Court held that the Act did not prohibit this type of pre-enforcement suit, that a case and controversy existed, that the issues presented were justiciable, and that no reasons had been presented by the Government to warrant declining jurisdiction on discretionary grounds. 235 F. Supp. 648. Recognizing that the subsequent decision of the Court of Appeals for the Third Circuit in *Abbott Laboratories v. Celebrezze*, 352 F. 2d 286, appeared to conflict with its holding, the District Court reaffirmed its earlier rulings but certified the question of jurisdiction to the

Court of Appeals for the Second Circuit under 28 U. S. C. § 1292 (b). The Court of Appeals affirmed the judgment of the District Court that jurisdiction to hear the suit existed as to three of the challenged regulations, but sustained the Government's contention that judicial review was improper as to a fourth. 360 F. 2d 677.

Each side below sought review here from the portions of the Court of Appeals' decision adverse to it, the Government as petitioner in *Gardner v. Toilet Goods Assn.*, No. 438, and the Toilet Goods Association and other plaintiffs in the present case. We granted certiorari in both instances, 385 U. S. 813, as we did in *Abbott Laboratories v. Gardner*, No. 39, 383 U. S. 924, because of the apparent conflict between the Second and Third Circuits. The two *Toilet Goods* cases were set and argued together with *Abbott Laboratories*.

In our decisions reversing the judgment in *Abbott Laboratories*, ante, p. —, and affirming the judgment in *Gardner v. Toilet Goods Assn.*, post, p. —, both decided today, we hold that nothing in the Food, Drug, and Cosmetic Act bars a pre-enforcement suit under the Administrative Procedure Act, 5 U. S. C. §§ 701-704 (recodified in Pub. Law 89-554, 80 Stat. 378), and the Declaratory Judgment Act, 28 U. S. C. § 2201. We nevertheless agree with the Court of Appeals that judicial review of this particular regulation in this particular context is inappropriate at this stage because, applying the standards set forth in *Abbott Laboratories v. Gardner*, ante, the controversy is not presently ripe for adjudication.

The regulation in issue here was promulgated under the Color Additive Amendments of 1960, a statute that revised and somewhat broadened the authority of the Commissioner to control the ingredients added to foods, drugs, and cosmetics that impart color to them. The Commissioner of Food and Drugs, exercising power delegated by the Secretary, 22 Fed. Reg. 1051, 25 Fed. Reg.

8625, under statutory authority "to promulgate regulations for the efficient enforcement" of the Act, § 701 (a), 21 U. S. C. § 371 (a), issued the following regulation after due public notice, 26 Fed. Reg. 679, and consideration of comments submitted by interested parties:

"(a) When it appears to the Commissioner that a person has:

"(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived;

"he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken." 28 Fed. Reg. 6445-6446; 21 CFR § 8.28.¹

The petitioners maintain that this regulation is an impermissible exercise of authority, that the FDA has long sought congressional authorization for free access to facilities, processes, and formulae (see, *e. g.*, the proposed "Drug and Factory Inspection Amendments of 1962," H. R. 11581, 87th Cong., 2d Sess.; Hearings before the House Committee on Interstate and Foreign Commerce on H. R. 11581 and H. R. 11582, 87th Cong., 2d

¹ The Color Additive Amendments provide for listings of color additives by the Secretary "if and to the extent that such additives are suitable and safe" § 706 (b) (1), 21 U. S. C. § 376 (b) (1). The Secretary is further authorized to provide "for the certification, with safe diluents or without diluents, or batches of color additives" § 706 (c), 21 U. S. C. § 376 (c). A color additive is "deemed unsafe" unless it is either from a certified batch or exempted from the certification requirement, § 706 (a), 21 U. S. C. § 376 (a). A cosmetic containing such an "unsafe" additive is deemed to be adulterated, § 601 (e), 21 U. S. C. § 361 (e), and is prohibited from interstate commerce. § 301 (a), 21 U. S. C. § 331 (a).

Sess., 67-74; H. R. 6788, 88th Cong., 1st Sess.), but that Congress has always denied the agency this power except for prescription drugs. § 704, 21 U. S. C. § 374. Framed in this way, we agree with petitioners that a "legal" issue is raised, but nevertheless we are not persuaded that the present suit is properly maintainable.

In determining whether a challenge to an administrative regulation is ripe for review a twofold inquiry must be made: first to determine whether the issues tendered are appropriate for judicial resolution, and second to assess the hardship to the parties if judicial relief is denied at that stage.

As to the first of these factors, we agree with the Court of Appeals that the legal issue as presently framed is not appropriate for judicial resolution. This is not because the regulation is not the agency's considered and formalized determination, for we are in agreement with petitioners that under this Court's decisions in *Frozen Food Express v. United States*, 351 U. S. 40, and *United States v. Storer Broadcasting Co.*, 351 U. S. 192, there can be no question that this regulation—promulgated in a formal manner after notice and evaluation of submitted comments—is a "final agency action" under § 10 of the Administrative Procedure Act, 5 U. S. C. § 704. See *Abbott Laboratories v. Gardiner*, ante, p. —. Also, we recognize the force of petitioners' contention that the issue as they have framed it presents a purely legal question: whether the regulation is totally beyond the agency's power under the statute, the type of legal issue that courts have occasionally dealt with without requiring a specific attempt at enforcement, *Columbia Broadcasting System v. United States*, 316 U. S. 407; cf. *Pierce v. Society of Sisters*, 268 U. S. 510, or exhaustion of administrative remedies, *Allen v. Grand Central Aircraft Co.*, 347 U. S. 535; *Skinner & Eddy Corp. v. United States*, 249 U. S. 557.

These points which support the appropriateness of judicial resolution are, however, outweighed by other considerations. The regulation serves notice only that the Commissioner *may* under certain circumstances order inspection of certain facilities and data, and that further certification of additives *may* be refused to those who decline to permit a duly authorized inspection until they have complied in that regard. At this juncture we have no idea whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order. The statutory authority asserted for the regulation is the power to promulgate regulations "for the efficient enforcement" of the Act, § 701 (a). Whether the regulation is justified thus depends not only, as petitioners appear to suggest, on whether Congress refused to include a specific section of the Act authorizing such inspections, although this factor is to be sure a highly relevant one, but also on whether the statutory scheme as a whole justified promulgation of the regulation. See *Wong Yang Sung v. McGrath*, 339 U. S. 33, 47. This will depend not merely on an inquiry into statutory purpose, but concurrently on an understanding of what types of enforcement problems are encountered by the FDA, the need for various sorts of supervision in order to effectuate the goals of the Act, and the safeguards devised to protect legitimate trade secrets (see 21 CFR § 130.14 (c)). We believe that judicial appraisal of these factors is likely to stand on a much surer footing in the context of a specific application of this regulation than could be the case in the framework of the generalized challenge made here.

We are also led to this result by considerations of the effect on the petitioners of the regulation, for the test of ripeness, as we have noted, depends not only on how adequately a court can deal with the legal issue presented, but also on the degree and nature of the regula-

tion's present effect on those seeking relief. The regulation challenged here is not analogous to those that were involved in *Columbia Broadcasting Co., supra*, and *Storer, supra*, and those other color additive regulations with which we deal in *Gardner v. Toilet Goods Assn., post, p. —*, where the impact of the administrative action could be said to be felt immediately by those subject to it in conducting their day-to-day affairs. See also *Federal Communications Comm'n v. American Broadcasting Co.*, 347 U. S. 284.

This is not a situation in which primary conduct is affected—when contracts must be negotiated, ingredients tested or substituted, or special records compiled. This regulation merely states that the Commissioner may authorize inspectors to examine certain processes or formulae; no advance action is required of cosmetics manufacturers, who since the enactment of the 1938 Act have been under a statutory duty to permit reasonable inspection of a "factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein." § 704 (a). Moreover, no irremediable adverse consequences flow from requiring a later challenge to this regulation by a manufacturer who refuses to allow this type of inspection. Unlike the other regulations challenged in this action, in which seizure of goods, heavy fines, adverse publicity for distributing "adulterated" goods, and possible criminal liability might penalize failure to comply, see *Gardner v. Toilet Goods Assn., post, p. —*, a refusal to admit an inspector here would at most lead only to a suspension of certification services to the particular party, a determination that can then be promptly challenged through an administrative procedure,² which

² See 21 CFR §§ 8.28 (b), 130.14-130.26. We recognize that a denial of certification might under certain circumstances cause inconvenience and possibly hardship, depending upon such factors as how

in turn is reviewable by a court.³ Such review will provide an adequate forum for testing the regulation in a concrete situation.

It is true that the administrative hearing will deal with the "factual basis" of the suspension, from which petitioners infer that the Commissioner will not entertain and consider a challenge to his statutory authority to promulgate the regulation.⁴ Whether or not this assumption is correct, given the fact that only minimal if any adverse consequences will face petitioners if they challenge the regulation in this manner, we think it wiser to require them to exhaust this administrative process through which the factual basis of the inspection order will certainly be aired and where more light may be

large a supply of certified additives the particular manufacturer may have, how rapidly the administrative hearing and judicial review are conducted, and what temporary remedial or protective provisions, such as compliance with a reservation pending litigation, might be available to a manufacturer testing the regulation. In the context of the present case we need only say that such inconvenience is speculative and we have been provided with no information that would support an assumption that much weight should be attached to this possibility.

³ The statute and regulations are not explicit as to whether review would lie, as Judge Friendly suggested, 360 F. 2d, at 687, to a Court of Appeals under §§ 701 (f) and 706 (d) of the Act, or to a District Court as an appeal from the Commissioner's "final order," 21 CFR § 130.26, under § 10 of the Administrative Procedure Act. See 21 CFR § 130.31; compare § 505, 21 U. S. C. § 355. For purposes of this case it is only necessary to ascertain that judicial review would be available to challenge any specific order of the Commissioner denying certification services to a particular drug manufacturer, and we therefore need not decide the statutory question of which forum would be appropriate for such review.

⁴ Petitioners also cite the Commissioner's refusal, in the context of a public hearing on certain drug regulations, to entertain objections to his statutory authority to promulgate them on the ground that "This is a question of law and cannot be resolved by the taking of evidence at a public hearing." 31 Fed. Reg. 7174.

8 TOILET GOODS ASSN. v. GARDNER.

thrown on the Commissioner's statutory and practical justifications for the regulation. Compare *Federal Security Adm'r v. Quaker Oats Co.*, 318 U. S. 218.⁵ Judicial review will then be available, and a court at that juncture will be in a better position to deal with the question of statutory authority. Administrative Procedure Act § 10 (e)(B)(3), 5 U. S. C., § 706 (2)(C).

For these reasons the judgment of the Court of Appeals is

Affirmed.

MR. JUSTICE DOUGLAS dissents for the reasons stated by Judge Tyler of the District Court, 235 F. Supp. 648, 651-652.

MR. JUSTICE BRENNAN took no part in the consideration or decision of this case.

⁵ See 3 Davis, *Administrative Law Treatise*, § 20.03, at p. 69 (1958).

SUPREME COURT OF THE UNITED STATES

No. 438.—OCTOBER TERM, 1966.

John W. Gardner, Secretary of Health, Education, and Wel- fare, et al., Petitioners, v. The Toilet Goods Association, Inc., et al.	}	On Writ of Certiorari to the United States Court of Appeals for the Second Circuit.
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[May 22, 1967.]

MR. JUSTICE HARLAN delivered the opinion of the Court.

In *Toilet Goods Assn. v. Gardner, ante*, p. —, we affirmed a judgment of the Court of Appeals for the Second Circuit holding that judicial review of a regulation concerning inspection of cosmetics factories was improper in a pre-enforcement suit for injunctive and declaratory judgment relief. The present case is brought here by the Government seeking review of the Court of Appeals' further holding that review of three other regulations in this type of action was proper. 360 F. 2d 677. We likewise affirm.

For reasons stated in our opinion in *Abbott Laboratories v. Gardner, ante*, p. —, we find nothing in the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 301 *et seq.*, that precludes resort to the courts for pre-enforcement relief under the Administrative Procedure Act, 5 U. S. C. §§ 701-704 (recodified in Pub. Law 89-554, 80 Stat. 378), and the Declaratory Judgment Act, 28 U. S. C. § 2201. And for reasons to follow, we believe the Court of Appeals was correct in holding that the District Court did not err when it refused to dismiss the complaint with respect to these regulations.

The regulations challenged here were promulgated under the Color Additive Amendments of 1960, 74 Stat.

397, 21 U. S. C. §§ 321-376. These statutory provisions, in brief, allow the Secretary of Health, Education, and Welfare and his delegate, the Commissioner of Food and Drugs, 22 Fed. Reg. 1051, 25 Fed. Reg. 8625, to prescribe conditions for the use of color additives in foods, drugs, and cosmetics. The Act requires clearance of every color additive in the form of a regulation prescribing conditions for use of that particular additive, and also certification of each "batch" unless exempted by regulation. A color additive is defined as "a dye, pigment, or other substance . . . [which] when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto . . .," 21 U. S. C. § 321(t)(1).

Under his general rule-making power, § 701 (a), 21 U. S. C. § 371 (a), the Commissioner amplified the statutory definition to include as color additives all diluents, that is, "any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body." 21 CFR § 8.1 (m). By including all diluents as color additives, the Commissioner in respondent's view unlawfully expands the number of items that must comply with the premarketing clearance procedure.

The Commissioner also included as a color additive within the coverage of the statute any "substance that, when applied to the human body results in coloring . . . unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives.'" 21 CFR § 8.1 (f). Respondents alleged that in promulgating this regulation the Commissioner again impermissibly

expanded the reach of the statute beyond the clear intention of Congress.

A third regulation challenged by these respondents concerns the statutory exemption for hair dyes that conform to a statutory requirement set out in § 601 (e), 21 U. S. C. § 361 (e). That requirement provides that hair dyes are totally exempt from coverage of the statute if they display a certain cautionary notice on their labels prescribing a "patch test" to determine whether the dye will cause skin irritation on the particular user. The Commissioner's regulation recognizes that the exemption applies to the Color Additive Amendments, but goes on to declare: "If the poisonous or deleterious substance in the 'hair dye' is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend the poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair." 21 CFR § 8.1 (u).

Respondents contend that this regulation too is irreconcilable with the statute: whereas the statute grants an across-the-board exemption to all hair dyes meeting the patch-test notice requirement, the regulation purports to limit that exemption to cover only those dyes as to which the test is "effective." Moreover, it is said, the regulation appears to limit the exemption only to the coloring ingredient of the dye, and to require clearance for all other components of a particular hair dye.

We agree with the Court of Appeals that respondents' challenge to these regulations is ripe for judicial review under the standards elaborated in *Abbott Laboratories v. Gardner*, ante, namely the appropriateness of the issues for judicial determination and the immediate severity of the regulations' impact upon the plaintiffs.

The issue as framed by the parties is a straightforward legal one: what general classifications of ingredients fall within the coverage of the Color Additive Amendments? Both the Government and the respondents agree that for any color additive, distribution is forbidden unless the additive is (1) listed in a Food and Drug Administration regulation as safe for use under prescribed conditions, and (2) comes from a "certified" batch, unless specifically exempted from the certification requirement. The only question raised is what sort of items are "color additives." The three regulations outlined above purport to elaborate the statutory definition; they include within the statutory term certain classes of items, *e. g.*, diluents, finished cosmetics, and hair dyes, that respondents assert are not within the purview of the statute at all. We agree with the District Court and the Court of Appeals that this is not a situation in which consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to enforce the regulations.¹ Rather, "to the extent that they purport to apply premarketing requirements to broad categories like finished products and non-coloring ingredients and define the hair-dye exemption, they appear, *prima facie*, to be susceptible of reasoned comparison with the statutory mandate without inquiry into factual issues that ought to be first ventilated before the agency." 360 F. 2d, at 685.

For these reasons we find no bar to consideration by the courts of these issues in their present posture. *Abbott*

¹ We use "necessarily" advisedly, because this case arises on a motion to dismiss. The District Court also denied respondents' motion for summary judgment, and called for an evidentiary hearing. If in the course of further proceedings the District Court is persuaded that technical questions are raised that require a more concrete setting for proper adjudication, a different issue will be presented.

Laboratories, Inc. v. Gardner, ante; United States v. Storer Broadcasting Co., 351 U. S. 192; *Frozen Food Express v. United States*, 351 U. S. 40.

This result is supported as well by the fact that these regulations are self-executing, and have an immediate and substantial impact upon the respondents. See *Abbott Laboratories v. Gardner, ante*, pp. —, —. The Act, as noted earlier, prescribes penalties for the distribution of goods containing color additives unless they have been cleared both by listing in a regulation and by certification of the particular batch. Faced with these regulations the respondents are placed in a quandary. On the one hand they can, as the Government suggests, refuse to comply, continue to distribute products that they believe do not fall within the purview of the Act, and test the regulations by defending against government criminal, seizure, or injunctive suits against them. We agree with the respondents that this proposed avenue of review is beset with penalties and other impediments rendering it inadequate as a satisfactory alternative to the present declaratory-judgment action.

The penalties to which cosmetic manufacturers might be subject are extensive. A color additive that does not meet the premarketing clearance procedure is declared to be "unsafe," § 706 (a), 21 U. S. C. § 376 (a), and hence "adulterated," § 601, 21 U. S. C. § 361 (e). It is a "prohibited act" to introduce such material into commerce, § 301, 21 U. S. C. § 331, subject to injunction, § 302, 21 U. S. C. § 332, criminal penalties, § 303, 21 U. S. C. § 333, and seizure of the goods, § 304 (a), 21 U. S. C. § 334 (a). The price of noncompliance is not limited to these formal penalties. Respondents note the importance of public good will in their industry, and not without reason fear the disastrous impact of an announcement that their cosmetics have been seized as "adulterated."

The alternative to challenging the regulations through noncompliance is, of course, to submit to the regulations and present the various ingredients embraced in them for premarketing clearance. We cannot say on this record that the burden of such a course is other than substantial, accepting, as we must on a motion to dismiss on the pleadings, the allegations of the complaint and supporting affidavits as true. The regulations in this area require separate petitions for listing each color additive, 21 CFR §§ 8.1 (f), (m), 8.4 (c), at an initial fee, subject to refunds, of \$2,600 a listing. 21 CFR § 8.50 (c). One respondent, Kolmar Laboratories, Inc., in affidavits submitted to the District Court, asserted that more than 2,700 different formulae would fall under the Commissioner's regulations and would cost some \$7,000,000 in listing fees alone. According to the allegations the company also uses 264 diluents which under the challenged regulations must be included as color additives as well. Moreover, a listing is not obtained by mere application alone. Physical and chemical tests must be made and their results submitted with each petition, 21 CFR § 8.4 (c), at a cost alleged by Kolmar as up to \$42,000,000. Detailed records must be maintained for each listed ingredient, 21 CFR § 8.26, and batches of listed items must ultimately be certified, again at a substantial fee, 21 CFR § 8.51.

Whether or not these cost estimates are exaggerated² it is quite clear that if respondents, failing judicial review at this stage, elect to comply with the regulations and await ultimate judicial determination of the validity of

² The Court of Appeals observed that "Very likely these figures are exaggerated" 360 F. 2d, at 682. The District Court stated that "While this amount is immediately suspect, there can be little doubt but that the added recordkeeping and laboratory testing costs in themselves will be extremely burdensome for all of the plaintiffs." 235 F. Supp. 648, 652. (Footnote omitted.)

them in subsequent litigation, the amount of preliminary paper work, scientific testing, and recordkeeping will be substantial. The District Court found in denying the motion to dismiss: "I conclude that in a substantial and practical business sense plaintiffs are threatened with irreparable injury by the obviously intended consequences of the challenged regulations, and that to resort to later piecemeal resolution of the controversy in the context of individual enforcement proceedings would be costly and inefficient, not only for the plaintiffs but as well for the public as represented by the defendants." 235 F. Supp. 648, 651.

Like the Court of Appeals, we think that this record supports those findings and conclusions. And as in *Abbott Laboratories, Inc.*, ante, we have been shown no substantial governmental interest that should lead us to reach a conclusion different from the one we have reached in that case. We hold that this action is maintainable.

Affirmed.

MR. JUSTICE BRENNAN took no part in the consideration or decision of this case.



SUPREME COURT OF THE UNITED STATES

Nos. 336, 39, AND 438.—OCTOBER TERM, 1966.

The Toilet Goods Association,
Inc., et al., Petitioners,
336 v.
John W. Gardner, Secretary
of Health, Education, and
Welfare, et al.

On Writ of Certiorari to
the United States Court
of Appeals for the Sec-
ond Circuit.

Abbott Laboratories et al.,
Petitioners,
39 v.
John W. Gardner, Secretary
of Health, Education, and
Welfare, et al.

On Writ of Certiorari to
the United States Court
of Appeals for the Third
Circuit.

John W. Gardner, Secretary
of Health, Education, and
Welfare et al., Petitioners,
438 v.
The Toilet Goods Association,
Inc., et al.

On Writ of Certiorari to
the United States Court
of Appeals for the Sec-
ond Circuit.

[May 22, 1967.]

MR. JUSTICE FORTAS, with whom THE CHIEF JUSTICE and MR. JUSTICE CLARK join, concurring in No. 336, and dissenting in Nos. 39 and 438.

I am in agreement with the Court in No. 336, *Toilet Goods Association v. Gardner*, that we should affirm the decision of the Court of Appeals for the Second Circuit holding that the authority of the Secretary of Health, Education, and Welfare to promulgate the regulation there involved may not be challenged by injunctive or declaratory judgment action. The regulation (herein-

after referred to as the "access regulation") was issued under the 1960 Color Additive Amendments to the Federal Food, Drug, and Cosmetic Act. 74 Stat. 397, 21 U. S. C. §§ 321-376. It requires that manufacturers afford employees of the agency access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates, and provides that the Commissioner "may immediately suspend certification service" so long as access is denied.

I am, however, compelled to dissent from the decisions of the Court in No. 39, *Abbott Laboratories v. Gardner*, and No. 438, *Gardner v. Toilet Goods Association*. These cases also involve regulations promulgated under the Federal Food, Drug, and Cosmetic Act. No. 438, like No. 336, arises under the Color Additive Amendments of 1960. The regulation implements the statutory definition of color additives to include diluents, finished cosmetics and certain hair dyes (the "definition regulation"). The regulation in No. 39 implements amendments to the Act adopted in 1962 by requiring that "every time" the proprietary or trade-mark name of a drug appears on labels and other printed materials, the "established" or generic name must accompany it (the "every time" regulation).

The issues considered by the Court are not constitutional questions. The Court does not rest upon any asserted right to challenge the regulations at this time because the agency lacks authority to promulgate the regulations as to the subject matters involved, or because its procedures have been arbitrary or unreasonable. Its decision is based solely upon respondents' claim of right to challenge these particular regulations at this time on the ground that they are erroneous exercises of the agency's power. It is solely on this point that the Court in these two cases authorizes threshold or pre-enforcement challenge by action for injunction and declaratory

relief to suspend the operation of the regulations in their entirety and without reference to particular factual situations.

With all respect, I submit that established principles of jurisprudence, solidly rooted in the constitutional structure of our Government, require that the courts should not intervene in the administrative process at this stage, under these facts and in this gross, shotgun fashion. With all respect, I submit that the governing principles of law do not permit a different result in these cases than in No. 336. In none of these cases is judicial interference warranted at this stage, in this fashion, and to test—on a gross, free-wheeling basis—whether the content of these regulations is within the statutory intendment. The contrary is dictated by a proper regard for the purpose of the regulatory statute and the requirements of effective administration; and by regard for the salutary rule that courts should pass upon concrete, specific questions in a particularized setting rather than upon a general controversy divorced from particular facts.

The Court, by today's decisions, has opened Pandora's box. Federal injunctions will now threaten programs of vast importance to the public welfare. The Court's holding here strikes at programs for the public health. The dangerous precedent goes even further. It is cold comfort—it is little more than delusion—to read in the Court's opinion that "It is scarcely to be doubted that a court would refuse to postpone the effective date of an agency action if the Government could show . . . that delay would be detrimental to the public health or safety." Experience dictates, on the contrary, that it can hardly be hoped that some federal judge somewhere will not be moved as the Court is here, by the regulated's cries of anguish and distress, to grant a disruptive injunction.

The difference between the majority and me in these cases is not with respect to the existence of jurisdiction to enjoin, but to the definition of occasions on which such jurisdiction may be invoked. I do not doubt that there is residual judicial power in some extreme and limited situations to enjoin administrative actions even in the absence of specific statutory provision where the agency has acted unconstitutionally or without jurisdiction—as distinguished from an allegedly erroneous action. But the Court's opinions in No. 39 and No. 438 appear to proceed on the principle that, even where no constitutional issues or questions of administrative jurisdiction or of arbitrary procedure are involved, exercise of judicial power to enjoin allegedly erroneous regulatory action is permissible unless Congress has explicitly prohibited it, provided only that the controversy is "ripe" for judicial determination. This is a rule that is novel in its breadth and destructive in its implications as illustrated by the present application. As will appear, I believe that this approach improperly and unwisely gives individual federal district judges a roving commission to halt the regulatory process, and to do so on the basis of abstractions and generalities instead of concrete fact situations, and that it impermissibly broadens the license of the courts to intervene in administrative action by means of threshold suit for injunction rather than by the method provided by statute.

The Administrative Procedure Act¹ and fundamental principles of our jurisprudence² insist that there must be some type of effective judicial review of final, substantive

¹ Recodified in 80 Stat. 378, 5 U. S. C. §§ 701-704.

² See *St. Joseph Stock Yards Co. v. United States*, 298 U. S. 38, 84 (1936) (concurring opinion of Mr. Justice Brandeis). Hart & Wechsler, *The Federal Courts and the Federal System* 312-340 (1953). Compare, 4 Davis, *Administrative Law Treatise*, § 28.18 (1958).

agency action which seriously affects personal or property rights. But "[a]ll constitutional questions aside, it is for Congress to determine how the rights which it creates shall be enforced In such a case the specification of one remedy normally excludes another." *Switchmen's Union v. Board*, 320 U. S. 297, 301 (1943). Where Congress has provided a method of review, the requisite showing to induce the courts otherwise to bring a governmental program to a halt may not be made by a mere showing of the impact of the regulation and the customary hardships of interim compliance. At least in cases where the claim is of erroneous action rather than the lack of jurisdiction or denial of procedural due process, a suit for injunctive or declaratory relief will not lie absent a clear demonstration that the type of review available under the statute would not be "adequate," that the controversies are otherwise "ripe" for judicial decision, and that no public interest exists which offsets the private values which the litigation seeks to vindicate. As I shall discuss, no such showing is or can be made here.

I.

Since enactment of the Federal Food, Drug, and Cosmetic Act in 1938, the mechanism for judicial review of agency actions under its provisions has been well understood. Except for specific types of agency regulations and actions to which I shall refer, judicial review has been confined to enforcement actions instituted by the Attorney General on recommendation of the agency. As the recurrent debate over this technique demonstrates, this restricted avenue for challenge has been deemed necessary because of the direct and urgent relationship of the field of regulation to the public health.³ It is this

³ See *Ewing v. Mytinger & Casselberry*, 339 U. S. 594, 601 (1950).

avenue that applies with respect to the regulations at issue in the present cases.

The scheme of the Act, in this respect, is as follows: "Prohibited acts" are listed in 21 U. S. C. § 331. Subsequent sections authorize the Attorney General to institute three types of proceedings. First, under 21 U. S. C. § 332, he may apply to the district courts of the United States for injunctive relief. If an injunction is violated, jury trial is assured on demand of the accused. Second, under 21 U. S. C. § 334, the Attorney General may institute libel proceedings in the district courts and seek orders for seizure of any misbranded or adulterated food, drug, device, or cosmetic. Third, criminal prosecution is authorized for violations, but before the Secretary may report a violation to the Attorney General for criminal prosecution, he must afford the affected person an opportunity to present his views. 21 U. S. C. §§ 333, 335.

The present regulations concededly would be reviewable in the course of any of the above proceedings. Apart from these general provisions, the Act contains specific provisions for administrative hearing and review in the courts of appeals with respect to regulations issued under certain, enumerated provisions of the Act—not including those here involved. These appear in § 701 (f) of the Act. 21 U. S. C. § 371 (f). Section 701, by subdivision (a), contains the Secretary's general authority, exercised in the present cases, to promulgate "regulations for the efficient enforcement of [the Act]." Subdivisions (e) and (f) provide for public hearings, administrative findings, and judicial review in a court of appeals with respect to those regulations specifically enumerated in subsection (e).⁴ The Court agrees that this procedure

⁴ 21 U. S. C. § 371 (e) refers only to regulations under § 341 (identity and quality standards for food), § 343 (j) (misbranded food purporting to serve special dietary purposes), § 344 (a) (cen-

applies only to the enumerated types of regulations and that the present regulations are unaffected. Then, as to the enumerated regulations which are subject to judicial review—and only as to them—subparagraph (6) of subsection (f) specifies that “the remedies provided for in this subsection (f) shall be “in addition to and not in substitution for any other remedies provided by law.” This “savings clause” does not apply or refer to regulations other than those enumerated, and the Court’s argument to the contrary is inconsistent with the clear wording and placement of the clause.⁵

ditions imposed on manufacture of food as the result of health requirements), § 346 (tolerances for pesticides), § 351 (b) (deviations from strength, quality, or purity standards, for drugs), § 352 (d) (warnings with respect to habit-forming drugs), and § 352 (h) (packing and labeling of deteriorative drugs). In addition, particular sections expressly incorporate the §§ 371 (f) and (g) procedures: § 356 (certain portions of regulations pertaining to certification of drugs containing insulin), § 357 (with respect to regulations dealing with antibiotic drugs). Finally, § 355 (h) provides that denials of certification for new drugs may be reviewed in the courts of appeals.

⁵ The savings clause, subdivision (6), of subsection (f), specifically and carefully refers to the “remedies provided for in *this* subsection.” (Emphasis added.) Its wording and placement would be anomalous if the savings clause were intended to have general applicability. The legislative history of the savings clause, and particularly the failure of more broadly conceived provisions to obtain acceptance by the Congress, corroborates the evidence of the clause’s ultimate language and position that it was to have restricted application. See Dunn, Federal Food, Drug, and Cosmetic Act 184, 225, 609–610 (1938) [hereinafter cited as Dunn].

Contrary to the majority’s contention, the reason for the clause and for its location in subsection (f) is clear and common-sensical. It was intended to save the remedies of injunction and declaratory judgment where the agency promulgated a subsection (e) regulation without the hearings and findings needed to permit review in the Court of Appeals. In short, as its placement indicates, it was intended to complete the scheme of pre-effectiveness review as to

At various times, § 701 has been amended to include types of regulations in addition to those initially subjected to § 701 (f). Indeed, in the congressional action which included enactment of statutory provisions here in issue, the 1960 Color Additive Amendments, 74 Stat. 397, 21 U. S. C. § 376; Congress amended § 701 (e) to include certain of the regulations authorized by the Color Additive Amendments. But, significantly, these did not include the regulations at issue in No. 336 and No. 438. The same is true with respect to the later Drug Amendments of 1962. Subsection (e) was again enlarged, but the provision involved in No. 39 was not included. These actions were taken in the course of vigorous debate as to the enforcement and review provisions which should be enacted with respect to the 1960 and 1962 amendments.

On a number of occasions Congress considered and rejected the proposal that district courts be given power to restrain by injunction the enforcement of regulations.⁶ The bill that became law in 1938 originally contained provisions for hearings and judicial review in the district courts of certain specified types of regulations (substantially those later enacted as § 701, *supra*). District courts were also empowered to enjoin "any regulation promulgated in accordance with Section 24" (which would include the regulations at issue in these cases,

those carefully enumerated regulations with respect to which Congress deemed pre-enforcement review to be advisable. It has no broader application.

It will come as a shock to the agency, Congress, and practitioners, that for almost 30 years this undetected, omnibus "savings clause" has slumbered in the Act.

⁶Section 23 of S. 2800, introduced in the 73d Cong., 2d Sess. (1934), for example, was such a provision and was expressly discussed on the floor of the Senate. 78 Cong. Rec. 8958-8959 (1934); Dunn 157-159. A successor bill, S. 5, 74th Cong., 1st Sess. (1935), contained a similar provision, § 702, and was approved by the Senate. 79 Cong. Rec. 8356 (1935). See Dunn 330-331, 510.

promulgated under § 701 (a)). S. 5, 75th Cong., 1st Sess. (1927). The House Committee eliminated the latter provision and substituted what became subsection (f). This draft authorized review in a district court of regulations under subsection (e) and of those orders only.⁷ Even this restricted provision for enjoining certain regulations met with bitter opposition because it "would postpone indefinitely the consumer protection" or would "hamstring" the Act's enforcement and "amount to a practical nullification . . . of the bill."⁸ The Conference Committee then drafted the bill which was enacted, including the House revision of the review provision which became § 701 except for a significant change: So concerned was the Congress lest the administration of the law should be subject to judicial intervention that even with respect to the specified regulations in subsection (e) the reviewing power was placed in the courts of appeals rather than in the district courts.⁹ This was to meet the criticism that "a single district judge could be found who would issue an injunction." But this is exactly what the Court today decrees. Rejected along with the original House proposal was the suggestion from the Department of Justice, set out at 83 Cong. Rec. 7892 (1938), that the Congress should leave review in the hands of the district courts' traditional injunctive powers—although the Court today resuscitates that lost cause, too.

As this Court held in *Ewing v. Mytinger & Casselberry*, 339 U. S. 594, 600-601 (1950), "This highly selective manner in which Congress has provided [in this Act] for judicial review reinforces the inference that the only review of the issue of probable cause [for seizure] was the one provided in the libel suit."

⁷ H. R. Rep. No. 2179, 75th Cong., 3d Sess. (1938).

⁸ *Id.*, Pt. II (minority statement).

⁹ Conference Rep. No. 2716, 75th Cong., 3d Sess. (1938).

In evaluating the destructive force and effect of the Court's action in these cases, it is necessary to realize that it is arming each of the federal district judges in this Nation with power to enjoin enforcement of regulations and actions under the federal law designed to protect the people of this Nation against dangerous drugs and cosmetics. Restraining orders and temporary injunctions will suspend application of these public safety laws pending years of litigation—a time schedule which these cases illustrate.¹⁰ They are disruptive enough, regardless of the ultimate outcome. The Court's validation of this shotgun attack upon this vital law and its administration is not confined to these suits, these regulations, or these plaintiffs—or even this statute. It is a general hunting license; and I respectfully submit, a license to mischief because it authorizes aggression which is richly rewarded by delay in the subjection of private interests to programs which Congress believes to be required in the public interest. As I read the Court's opinion, it does not seriously contend that Congress authorized or contemplated this type of relief. It does not rest upon the argument that Congress intended that injunctions or threshold relief should be available. The Court seems to announce a doctrine, which is new and startling in administrative law, that the courts, in determining whether to exercise jurisdiction by injunction, will not look to see whether Congress intended that the parties should resort to another avenue of review, but will be governed by whether Congress has "prohibited" injunctive relief. The Court holds that "judicial review of a final agency action by an aggrieved person will not

¹⁰ The "every time" regulation was promulgated about four years ago, on June 20, 1963, 28 Fed. Reg. 6375. As a result of litigation begun in September of 1963, it has not yet been put into force. The "definition" regulation and the "access" regulation with respect to color additives were promulgated on June 22, 1963, 21 CFR 8.1 *et seq.* Litigation was begun in November of 1963, and the regulations are not yet operative.

be cut off unless there is persuasive reason to believe that such was the purpose of Congress." As authority for this, the Court produces little support. *Board of Governors v. Agnew*, 329 U. S. 441 (1947), involved removal from office of certain bank directors. Had the Court not authorized review, the aggrieved individuals could only test the correctness of the administrator's decision by ignoring it and risking a prison term of five years. No evidence of congressional hostility to review was adduced.¹¹ *Heikkila v. Barber*, 345 U. S. 229 (1953), does not even remotely support the Court's contention. On the contrary, it holds that a provision in the Immigration and Naturalization Act to the effect that the decision of the Attorney General is "final" in deportation cases precludes direct attack upon a deportation order by means of suits for injunction or declaratory relief. What might be termed the other personal liberties cases relied upon by the Court are discussed below. But in cases like the present, where courts and administrative agencies both function, it has always—to this date—been accepted that the intention of Congress—not its mere failure to prohibit—will be faithfully searched out by the courts and will be implemented except in the unusual and extraordinary situations where the result would be essentially to leave the parties without any adequate right to judicial review. Compare *Leedom v. Kyne*, 358 U. S. 184 (1958), with *Switchmen's Union v. Board*, *supra*; *Myers v. Bethlehem Shipbuilding Corp.*, 303 U. S. 41 (1938); and *Adams v. Nagle*, 303 U. S. 532 (1938).

¹¹ As to the other nonpersonal liberty cases cited by the Court: In *Shields v. Utah Idaho R. Co.*, 305 U. S. 177 (1938), the Government did not oppose resort to the injunction remedy, and the Court enumerated special circumstances why that remedy was peculiarly needed. *Id.*, at 183-184. And in *Stark v. Wickard*, 321 U. S. 288 (1948), the Court noted that the aggrieved parties had no other forum in which to contest the order in question, and it found "plain" evidence of a congressional intent to allow review.

In effect, the Court says that the Food, Drug, and Cosmetic Act has always authorized threshold injunctions or declaratory judgment relief: that this relief has been available since the enactment of the law in 1938, and that it would have been granted in appropriate cases which are "ripe" for review. I must with respect characterize this as a surprising revelation. Despite the highly controversial nature of many provisions of such regulations under the Act, this possibility has not been realized by ingenious and aggressive counsel for the drug and food and cosmetic industry until this time. The Court's opinion and the briefs cite only a single case in which such relief has been granted prior to the present cases, and that preceded enactment of the present statutory scheme. *Morgan v. Nolan*, 3 F. Supp. 143 (D. C. S. D. Ind. 1933), *aff'd*, 69 F. 2d 471 (C. A. 7th Cir. 1934). The fact of the matter is that, except for the instances enumerated in §§ 701 (e) and (f), the avenue for attack upon the statute and regulations has been by defense to specific enforcement actions by the agency. Congress has been well aware of this for more than a generation that the statute has been in effect.¹²

Where a remedy is provided by statute, I submit that it is and has been fundamental to our law, to judicial administration, to the principle of separation of powers in our Constitution, that the courts will withhold equitable or discretionary remedies unless they conclude that the statutory remedy is inadequate. Even then, as the Court recognizes, the case must be "ripe" or appropriate for threshold judicial review. Any other doctrine than this—any doctrine which so far departs from judicial restraint and judicial recognition of the power of the

¹² Indeed, Congressman Lea, principal floor manager for the bill which became the 1938 Act, told his colleagues that the review provisions of the new bill were not retroactive, and that pre-existing regulations were therefore unreviewable unless re-enacted. 83 Cong. Rec. 7776-7777 (1938).

Congress and the administrative agencies—is bound to be disruptive. It would mean that provisions in regulatory statutes and regulations of a wide variety of administrative agencies would be subject to threshold attack because Congress has not, in addition to providing judicial review by prescribed procedures, also said to the courts, “thou shalt not enjoin *in limine*.”

The limited applicability of the Administrative Procedure Act in these cases is entirely clear. That Act requires that unless precluded by Congress final agency action of the sorts involved here must be reviewable at some stage, and it recognizes that such review must be “adequate.” It merely presents the question in these cases. It does not supply an answer. Certainly, it would be revolutionary doctrine that the Administrative Procedure Act authorizes threshold suits for injunction even where another and adequate review provision is available. The Court refers to the Administrative Procedure Act as “seminal.” It is, in a real sense; but its seed may not produce the lush, tropical jungle of the doctrine that the Court will permit agency action to be attacked *in limine* by suit for injunction or declaratory action unless Congress expressly prohibits review of regulatory action. See 4 Davis, Administrative Law Treatise, § 22.08 (1958).

I submit that if we are to judge and not to legislate policy, we should implement and not contradict the program laid out by the Congress. Congress did not intend that the regulations at issue in this case might be challenged in gross, apart from a specific controversy, or in the district courts, or by injunction or declaratory judgment action. On the contrary, the clear intent was that the regulations, being to protect the consumer from unsafe, potentially harmful, and “misbranded” foods, drugs, devices, and cosmetics, were to be subject to challenge only by way of defense to enforcement proceedings. It was Congress’ judgment, after much con-

roversy, that the special nature of the Act and its administration required this protection against delay and disruption. We should not arrogate to ourselves the power to override this judgment. Not a single case cited by the majority in which agency action was held reviewable arose against this kind of background of legislative hostility to threshold review in the district courts.

The Court is in error, I submit, in its approach to this problem; and, as I shall attempt to show, it is in error in its decision that, even given this permissive approach to the use of judicial injunctive power, these controversies are "ripe" or appropriate for decision.

II.

I come then to the questions whether the review otherwise available under the statute is "adequate," whether the controversies are "ripe" or appropriate for review in terms of the evaluation of the competing private and public interests. I discuss these together because the questions of adequacy and ripeness or appropriateness for review are interrelated. I again note that no constitutional issues are raised, and, indeed, no issues as to the authority of the agency to issue regulations of the general sort involved. The only issue is whether that authority was properly exercised.

There is, of course, no abstract or mechanical method for determining the adequacy of review provisions. Where personal status or liberties are involved, the courts may well insist upon a considerable ease of challenging administrative orders or regulations. Cf. *Rusk v. Cort*, 369 U. S. 367 (1962); but cf. *Heikkila v. Barber*, 345 U. S. 229 (1953).¹³ But in situations where a regulatory scheme designed to protect the public is involved, this Court has held that postponement of the opportunity

¹³ See Jaffe, *Judicial Control of Administrative Action* 372.

to obtain judicial relief in the interests of avoiding disruption of the regulatory plan is entirely justifiable. *Ewing v. Mytinger & Casselberry*, 339 U. S. 594 (1950); cf. *Myers v. Bethlehem Shipbuilding Corp.*, 303 U. S. 41 (1938).¹⁴ The *Ewing* case dramatically illustrates the point. It involves the same statute and enforcement plan as are now before us. Appellee filed suit in the United States District Court to restrain enforcement of the provisions of the Food, Drug, and Cosmetic Act which authorizes multiple seizure of misbranded products. Appellee claimed that the provision was unconstitutional under the Due Process Clause, and that the agency had acted arbitrarily "in instituting" (through the Attorney General) multiple seizures without affording appellees an opportunity for hearing as to whether there was "probable cause" for the seizures. A three-judge district court was convened. It held for appellees on both issues and granted an injunction. This Court reversed on the grounds that no hearing is necessary for the administrative determination of probable cause, and that, in any event, the District Court had no jurisdiction to review that determination.¹⁵

¹⁴ In *Ewing*, 339 U. S., at 599, a case under the Federal Food, Drug, and Cosmetic Act, the Court held "it is not a requirement of due process that there be judicial inquiry before discretion can be exercised. It is sufficient, where only property rights are concerned, that there is at some stage an opportunity for a hearing and a judicial determination. *Phillips v. Commissioner*, 283 U. S. 589, 596-597; *Bowles v. Willingham*, 321 U. S. 503, 520; *Yakus v. United States*, 321 U. S. 414, 442-443."

¹⁵ Where Congress has created a right but provided no avenue for judicial protection against its obliteration, suit for injunctive relief may be available under 28 U. S. C. § 1337, relating to proceedings "arising under any Act of Congress regulating commerce or protecting trade and commerce against restraints and monopolies." See *Leedom v. Kyne*, 358 U. S. 184 (1958), where this Court authorized suit in the district courts to set aside an NLRB

It is no answer to *Ewing* to point out, as the Court does, that the precise determination attacked by the plaintiff was that of probable cause for recommending multiple seizures. The important point is that the Court held that the processes of the District Court could not be invoked except in the enforcement action provided by Congress. The following quotation from MR. JUSTICE DOUGLAS' opinion for the Court demonstrates the controlling force of *Ewing* in the present case:

"Judicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the Act. Congress made numerous administrative determinations under the Act reviewable by the courts. . . . This highly selective manner in which Congress has provided for judicial review reinforces the inference that the only review of the issue of probable cause which Congress granted was the one provided in the libel suit. Cf. *Switchmen's Union v. Board*, 320 U. S. 297, 305-306. . . . If the District Court can step in, stay the institution of seizures, and bring the administrative regulation to a halt until it hears the case, the public will be denied the speedy protection which Congress provided by multiple seizures."

In *Ewing*, the company's only recourse was to defend in the seizure actions, availing itself of consolidation of the multiple suits if it so desired. 359 U. S., at 602. Despite the hardship and destructive publicity of multiple seizures—a more serious variety of the kind of hardship which seems profoundly to affect the Court in the present cases, this Court refused to hold that the

certification of a bargaining unit in which the Board had included both supervisory and nonsupervisory personnel—concededly without authority of statute. But cf. *Switchmen's Union v. Board*, 320 U. S. 297 (1943).

remedy of judicial review by defense in these actions was inadequate. On the contrary, it held that "Congress weighed the potential injury to the public from the misbranded articles against the injury to the purveyor of the article from a temporary interference with its distribution and decided in favor of the speedy, preventive device of multiple seizures." 355 U. S., at 601.

I submit that this Court's action in Nos. 39 and 438 sharply departs from *Ewing* and from the principles of judicial restraint and respect for congressional enactments and administrative agencies which have to this day been fundamental to our jurisprudence. The Court refers in passing to the injunctions here as "traditional avenues of judicial relief." But there is nothing "traditional" about the courts providing injunctive relief against agency action in situations where the Congress has prescribed another avenue which is available to the plaintiffs. Eloquent testimony of this is the paucity of pertinent precedents.

The three decisions of this Court principally relied upon by the majority here are primarily noteworthy for their difference rather than their analogy. In each of them the particular statutory scheme involved expressly provided for the jurisdiction of the court in which the suit was brought. In none of them is the action maintained despite congressional provision of another and different remedy.

Columbia Broadcasting System v. United States, 316 U. S. 407 (1942), concerned a regulation promulgated by the FCC which would have refused a license to any station which entered into defined types of network contracts. CBS, a network and not a station licensee, brought an action to enjoin enforcement of the regulation, claiming that it was beyond the Commission's power. The action was brought under § 402 (a) of the Communications Act itself which makes applicable the

provisions of the Urgent Deficiencies Act to "suits to enforce, enjoin," etc., any order of the Commission with certain exceptions not here relevant. Thus, the statute itself provided for injunctive action against orders of the Commission. The only problem in the case was whether the particular order was "reviewable" at all on suit of CBS and, if so, whether the action was premature—not whether the courts might, consistently with the congressional scheme, entertain suit for injunction in proper circumstances, because that was settled by specific provisions in the Act. The Court held that the action could be maintained. And it held that CBS had no adequate alternative remedy. At most, CBS could have intervened in a proceeding controlled by a station applying for a license—if there were such a proceeding.¹⁰ The Court therefore held that CBS could challenge the regulation before it was invoked against a licensee. This is a far cry from the present case in which *despite* the absence of statutory authorization of district court jurisdiction over the injunctive procedure, and in face of the regulatory design, respondents seek to invoke the courts' general equity power to override what appears to be the studied and deliberate intention of the Congress.

In *United States v. Storer Broadcasting Co.*, 351 U. S. 192 (1956), the FCC promulgated a rule limiting to five the number of television stations which would be licensed to a single person. The same day it denied, on the basis of the rule, an application by Storer, who owned five stations, for an additional station. Storer appealed, not to the District Court, but to the Court of Appeals, for review of the Commission's rulemaking order. The Court of Appeals had jurisdiction by specific provision of the statute to entertain petitions to review final orders of the Commission upon application of "any party ag-

¹⁰ As a leading commentator has noted, the basic issue was that of CBS' standing. Jaffe, *op. cit. supra*, at 394.

grieved." 5 U. S. C. § 1034. This Court held that Storer had standing to maintain the petition for review, that the rule was a "final order" for review purposes and that the controversy with respect to the limitation rule was "ripe" for review. Again, the important point to note is that the case did not involve the assertion of district court jurisdiction in the absence of statute, or the overriding of administrative design or congressional intent. Storer utilized a procedure expressly made available by the statute. It sought review in the Court of Appeals where the Commission action was reviewed on the basis specified by statute, including the weight given to the agency findings and record. It did not commence a separate action, not provided for in the statute, in which the District Court's original jurisdiction was invoked. *Storer*, in brief, involves an action pursuant to the statute, and not in conflict with its plan as is true of the present cases.

The third case is *Frozen Food Express v. United States*, 351 U. S. 40 (1956). The ICC issued an order, after investigation and hearing, listing commodities which it found not to be "agricultural" for purposes of an exemption from the requirement of obtaining a certificate of convenience and necessity under the Interstate Commerce Act. A motor carrier sued in the United States District Court to enjoin and set aside the Commission's order. The statute under which the suit was brought expressly gives the district courts jurisdiction to enjoin, etc., "any order of the Interstate Commerce Commission." 28 U. S. C. § 1336. Accordingly, here, too, there was no question of the courts furnishing a forum which the regulatory statute did not provide. This case, like *Columbia Broadcasting* and *Storer*, *supra*, therefore, does not touch the key problem of the instant cases. It is relevant only on the issue of "ripeness"—an intensely particularized inquiry involving considerations which, as

I shall discuss, should lead to rejection of the instant actions.¹⁷

Considering the impact of these three cases on the problem of "ripeness" in the instant cases, I first note that each of these cases is, in effect, two-dimensional. The meaning, effect, and impact of the accused rule or decision are clear, simple, and obvious. Neither is part of the warp and woof of an elaborate administrative pattern, intimately woven into the congressional design. None of them is apt to take different shape or to be modified by practical administrative action. None of them is subject to the give-and-take of the administrative process as it works, for example, in the realities of the complex world of food, drug, and cosmetic regulation. None of them is subject to exception upon application. None of them depends upon the independent judgment of the Attorney General for enforcement. These are stark, simple, two-dimensional regulations which do not depend upon the specifics of a particular situation for judgment as to their consonance with statutory authority nor are they subject to change in the process of administrative application. In short, in the three cases the courts proceeded within the procedural framework enacted by Congress, and the circumstances were such that the courts could make a sensible, realistic judgment as to whether the administrative rule matched the statutory authority.¹⁸ These factors are entirely absent in the present cases. Analysis of the regulations in the present cases will, I believe, demonstrate the point.

¹⁷ Mr. Justice HARLAN dissented in *Frozen Food* on the ground that "the case falls squarely within those carefully developed rules which require that judicial intervention be withheld until administrative action has reached its complete development." 351 U. S., at 45.

¹⁸ Although *Frozen Food Express* involved problems of definition, they were not comparable to the complex, subtle, technical considerations involved in the "definition" or "every time" regulations here.

In No. 336 (involving the regulation requiring "free access" to plants, processes, and formulae with respect to all "color additives") the Court concludes "that the legal issue as presently framed is not appropriate for judicial resolution." It bases its conclusion upon two factors: (1) that the Secretary may or may not order inspection, and, if denied access, he may or may not decide to use the authority of the regulation to withdraw or suspend certification without which the manufacturer may not continue his business in the products; and (2) that judgment as to whether the regulation is authorized depends upon an understanding of the types of enforcement problems encountered by FDA, the need for supervision and the safeguards devised to protect legitimate trade secrets. The Court also says that it is an adequate remedy for the manufacturer to defer challenge until after access is demanded and denied and further certification services by the agency are suspended. The suspension of certification services means a shutdown, at least *pro tanto*, but the Court says, with an optimism which is probably not shared by the industry, that "prompt" challenge through administrative procedure and court review can then be had.

Precisely the same considerations demonstrate, I submit, that the regulations in No. 39 and No. 438 should similarly be immune from attack in these suits. In No. 438, the accused regulations were also issued under § 701 (a), the general power to promulgate regulations for the efficient administration of the Act, specifically the 1960 amendments to promote "safety-in-use" of color additives. As the Court states, by the regulations in No. 438 the Commissioner "amplified the statutory definition" of color additives to include diluents and certain cosmetics and hair dyes. By provisions in the statute, 21 U. S. C. § 376 (a)(1)(A), a product containing a "color additive" shall be deemed "adulterated" unless

the color additive and its proposed use have been submitted to FDA, tested and listed in an FDA regulation as safe and unless the particular additive comes from a certified batch, or has been exempted from certification. Distribution of a product without compliance runs the risk of seizure, injunction, or criminal prosecution upon action of the Attorney General. Again, there is no question that the Commissioner could refine and "amplify" the definition of "color additives." The argument is whether he could do it in this particular way, to include these particular items.

Now, with all respect, I submit that this controversy is clearly, transparently and obviously unsuited to adjudication by the courts *in limine* or divorced from a particular controversy. Every reason advanced in No. 336 (the access regulation) is applicable here with equal or greater force to repel this effort to secure judicial review at this stage. (1) In No. 336, the Court pointed out that the Commissioner might or might not demand access and withdraw certification in a particular case. Similarly, in the present case it is impossible to ascertain at this stage how and whether in a particular situation the regulation will apply to a particular situation. First and most obvious is the fact that any manufacturer may apply for an exemption from the regulation if, as applied to his particular situation, it is unfair or unduly burdensome or—more significantly—if it falls outside of the statutory intendment. And even more than in the case of the free access regulation, the definitional regulation is not self-enforcing. Indeed, in respect of the access regulation the Commissioner may resort to a measure of self-help by withholding certification services, whereas if the FDA wishes to take action against a manufacturer who refuses to submit a "color additive" to the agency on the ground that it is not covered, the agency must institute an independent proceeding in court which it

can do only if the Attorney General agrees with its conclusions.

(2) In No. 336, the Court was influenced by the obvious fact that adjudication of the legality of the access regulation requires an understanding of the enforcement problems of the agency and the actual needs for supervision. I agree. But I respectfully suggest that if this is true of a simple investigatory and enforcement regulation like that requiring access to plants and processes, it is much more compelling in respect of a complex regulation defining "color additives." How, for example, can a court possibly judge whether a substance should be included in the definition outside of the context of a specific controversy and in the absence of detailed information as to the agency problem?

The Court, however, describes the issue in No. 438 as "a straightforward legal one: what types of ingredients fall within the coverage of the Color Additive Amendments." The Court says that "this is not a situation in which consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of specific attempt to enforce the regulations." With all respect, these statements are totally divorced from reality. For example, the statute itself includes within the definition of a "color additive" any "other substance" which "when added or applied to a food, drug or cosmetic, or to the human body or any part thereof, is capable [alone or through reaction with other substance] of imparting color thereto." 21 U. S. C. § 321.(t)(1). Can it be seriously contended that the question, for example, whether a particular diluent—solvent or substance serving to dilute—meets this definition is "a straightforward legal one," decision of which would not "necessarily be facilitated" if raised in specific context? I note that the Court recognizes the frailty of its pronouncement in a footnote in which it says that "If in the course of further

proceedings the District Court is persuaded that technical questions are raised that require a more concrete setting for proper adjudication, a different issue will be presented"! But I submit, with respect, that this question which, even standing alone, would dictate our rejection of the action in No. 438, can and must be faced, here and now; and the answer to it is clear and obvious. It is clear beyond question, merely on the basis of the nature of the agency action, that these regulations on their face raise questions which should not be adjudicated in the abstract and in the general, but which require a "concrete setting" for determination. A threshold injunction is entirely unsuited in these circumstances. It places the administration of a public-safety statute at the mercy of counsel's ability to marshal and deploy horrible examples which logic may accommodate, but the reality of administration would repel. Our training as lawyers and judges, our respect for the administrative process, and our awareness of the complexities of life should warn us not to fall into the trap of abstract, generalized, gross review.

The regulation in No. 39 relates to a 1962 amendment to the Act requiring manufacturers of prescription drugs to print on the labels or other printed material, the "established name" of the drug "prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug." 21 U. S. C. § 352 (e) (1). Obviously, this requires some elucidation, either case-by-case or by general regulation or pronouncement, because the statute does not say that this must be done "every time," or only once on each label or in each pamphlet, or once per panel, etc., or that it must be done differently on labels than on circulars, or doctor's literature than on directions to the patients, etc. This is exactly the traditional purpose and function of an administrative agency. The Commissioner, acting by delega-

tion from the Secretary, took steps to provide for the specification. He invited and considered comments and then issued a regulation requiring that the "established name" appear every time the proprietary name is used. A manufacturer—or other person who violates this regulation—has mislabeled his product. The product may be seized; or injunction may be sought; or the mislabeler may be criminally prosecuted. In any of these actions he may challenge the regulation and obtain a judicial determination.

The Court, however, moved by petitioners' claims as to the expense and inconvenience of compliance and the risks of deferring challenge by noncompliance, decrees that the manufacturers may have their suit for injunction at this time and reverses the Third Circuit. The Court says that this confronts the manufacturer with a "real dilemma." But the fact of the matter is that the dilemma is no more than citizens face in connection with countless statutes and with the rules of the SEC, FTC, FCC, ICC, and other regulatory agencies. This has not heretofore been regarded as a basis for injunctive relief unless Congress has so provided. The overriding fact here is—or should be—that the public interest in avoiding the delay in implementing Congress' program far outweighs the private interest; and that the private interest which has so impressed the Court is no more than that which exists in respect of most regulatory statutes or agency rules. Somehow, the Court has concluded that the damage to petitioners if they have to engage in the required redesign and reprint of their labels and printed materials without threshold review outweighs the damage to the public of deferring during the tedious months and years of litigation a cure for the possible danger and asserted deceit of peddling plain medicine under fancy trademarks and for fancy prices which, rightly or wrongly, impelled the Congress to enact this

legislation. I submit that a much stronger showing is necessary than the expense and trouble of compliance and the risk of defiance. Actually, if the Court refused to permit this blunderbuss assault, experience and reasonably sophisticated commonsense show that there would be orderly compliance without the disaster so dramatically predicted by the industry, reasonable adjustments by the agency in real hardship cases, and where extreme intransigence involving substantial violations occurred, enforcement actions in which legality of the regulation would be tested in specific, concrete situations. I respectfully submit that this would be the correct and appropriate result. Our refusal to respond to the vastly overdrawn cries of distress would reflect not only healthy skepticism, but our regard for a proper relationship between the courts on the one hand and Congress and the administrative agencies on the other. It would represent a reasonable solicitude for the purposes and programs of the Congress. And it would reflect appropriate modesty as to the competence of the courts. The courts cannot properly—and should not—attempt to judge in the abstract and generally whether this regulation is within the statutory scheme. Judgment as to the “every time” regulation should be made only in light of specific situations, and it may differ depending upon whether the FDA seeks to enforce it as to doctor’s circulars, pamphlets for patients, labels, etc.

I submit, therefore, that this invitation to the courts to rule upon the legality of these regulations in these actions for injunction and declaratory relief should be firmly rejected. There is nothing here approaching the stringent showing that should be required before the courts will undertake to provide a remedy that Congress has not authorized but which, on the contrary, it has deliberately declined to afford. Petitioners have a remedy and there are no special reasons to relieve them of

the necessity of deferring their challenge to the regulations until enforcement is undertaken. In this way, and only in this way, will the administrative process have an opportunity to function—to iron out differences, to accommodate special problems, to grant exemptions, etc. The courts do not and should not pass on these complex problems in the abstract and the general—because these regulations peculiarly depend for their quality and substance upon the facts of particular situations. We should confine ourselves—as our jurisprudence dictates—to actual specific, particularized cases and controversies, in substance as well as in technical analysis. And we should repel these attacks, for we have no warrant and no reason to place these programs, essential to the public interest, and many others which this Court's action today will affect, at the peril of disruption by injunctive orders which can be issued by a single district judge. In short, the parties have an "adequate remedy" to test the regulations; these controversies are not "ripe" for judicial decision; and it is not appropriate that the courts should respond to the call for this private relief at disproportionate burden to the public interest. With all respect, we should refuse to accept the invitation to abandon the traditional insistence of the courts upon specific, concrete facts, and instead entertain this massive onslaught in which it will be utterly impossible to make the kind of discrete judgments which are within judicial competence. With all respect, we should not permit the administration of a law of the Congress to be disrupted by this non-adjudicable mass assault.

SUPREME COURT OF THE UNITED STATES

Nos. 39 AND 438.—OCTOBER TERM, 1966.

Abbott Laboratories et al.,
Petitioners,

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v.

John W. Gardner, Secretary of Health, Education, and Welfare, et al.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

John W. Gardner, Secretary of Health, Education, and Welfare, et al.,
Petitioners,

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v.

The Toilet Goods Association, Inc., et al.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit.

[May 22, 1967.]

MR. JUSTICE CLARK, dissenting.

I join my Brother FORTAS' dissent. As he points out the regulation here merely requires common honesty and fair dealing in the sale of drugs. The pharmaceutical companies, contrary to the public interest, have through their high-sounding trademarks of long established medicines deceitfully and exorbitantly extorted high prices therefor from the sick and the infirm. Indeed, I was so gouged myself just recently when I purchased some ordinary eyewash drops and later learned that I paid 10 times the price the drops should have cost. Likewise, a year or so ago I purchased a brand name drug for the treatment of labyrinthitis at a cost of some \$12, which later I learned to buy by its established name for about \$1.

The Court says that its action in so sabotaging the public interest is required because the laboratories will

have "to change all their labels, advertisements, and promotional materials . . . destroy stocks of printed matter; and they must invest heavily in new printing type and new supplies." I submit that this is a lame excuse for permitting the continuance of such a dishonest practice. Rather than crying over the plight that the laboratories have brought on themselves the Court should think more of the poor ailing folks who suffer under the practice. I dare say that the practice has prevented millions from obtaining needed drugs because of the price. The labels involved here mislead the public by passing off ordinary medicines as fancy cures. The Secretary was right in directing that the practice be stopped.

I hope that the Congress will not delay in amending the Act to close this judicial extortion that the Court has unwisely opened up for the pharmaceutical companies.